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Prior Authorization Guideline

GL-56524 Actimmune

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2020
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Actimmune	
Diagnosis	Chronic Granulomatous Disease (CGD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of chronic granulomatous disease

Product Name: Actimmune	
Diagnosis	Chronic Granulomatous Disease (CGD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Actimmune

Product Name: Actimmune	
Diagnosis	Severe, Malignant Osteopetrosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe, malignant osteopetrosis

Product Name: Actimmune	
Diagnosis	Severe, Malignant Osteopetrosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Actimmune

Product Name: Actimmune	
Diagnosis	Primary Cutaneous Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

- Mycosis fungoides (MF)
- Sézary syndrome (SS)

Product Name: Actimmune	
Diagnosis	Primary Cutaneous Lymphomas
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Actimmune

Product Name: Actimmune	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Actimmune will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Product Name: Actimmune	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Actimmune therapy

2 . Revision History

Date	Notes
11/6/2019	New Guideline.

Prior Authorization Guideline

GL-104188 Adbry

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/1/2022

1 . Criteria

Product Name: Adbry	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of moderate-to severe chronic atopic dermatitis

AND

1.1.2 One of the following

1.1.2.1 History of failure, contraindication, or intolerance to ALL of the following topical therapies: (document drug, date of trial, and/or contraindication to medication)

- One Medium to very-high potency topical corticosteroid [e.g., Elocon (mometasone furoate), Synalar (fluocinolone acetonide), Lidex (fluocinonide)] (See Table 1 in background section)
- One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]
- Eucrisa (crisaborole)

OR

1.1.2.2 Patient is currently on Adbry therapy

OR

1.2 Both of the following:

1.2.1 Diagnosis of chronic atopic dermatitis that has been determined to be severe based on physician assessment

AND

1.2.2 One of the following:

1.2.2.1 History of failure, contraindication, or intolerance to BOTH of the following topical therapies: (document drug, date of trial, and/or contraindication to medication)

- One Medium to very-high potency topical corticosteroid [e.g., Elocon (mometasone furoate), Synalar (fluocinolone acetonide), Lidex (fluocinonide)] (See Table 1 in background section)
- One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]

OR

1.2.2.2 Patient is currently on Adbry therapy

AND

2 - Patient is not receiving Adbry in combination with another biologic medication [e.g., Dupixent (dupilumab), Xolair (omalizumab)]

AND

3 - Prescribed by ONE of the following:

- Dermatologist
- Allergist
- Immunologist

Product Name: Adbry	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Adbry therapy

AND

2 - Patient is not receiving Adbry in combination with another biologic medication [e.g., Dupixent (dupilumab), Xolair (omalizumab)]

AND

3 - Prescribed by ONE of the following:

- Dermatologist
- Allergist
- Immunologist

2 . Background

Benefit/Coverage/Program Information

Table 1 Relative potencies of topical corticosteroids

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5

Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1
	Triamcinolone acetonide	Cream, ointment, lotion	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

3 . Revision History

Date	Notes
3/1/2022	New

Prior Authorization Guideline

GL-108175 Afinitor

Formulary

Formulary Note

Guideline Note:

Effective Date:	8/1/2022

1 . Criteria

Product Name: Brand Afinitor, generic everolimus, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Neuroendocrine tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of one of the following:	

- Neuroendocrine tumors of pancreatic origin
- Neuroendocrine tumors of gastrointestinal origin
- Neuroendocrine tumors of lung origin
- Neuroendocrine tumors of thymic origin

AND

2 - Disease is progressive

AND

3 - One of the following:

- Disease is unresectable
- Disease is locally advanced
- Disease is metastatic

Product Name: Brand Afinitor, generic everolimus, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Neuroendocrine Tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Renal cell cancer, Kidney Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced renal cell cancer/kidney cancer

AND

2 - Disease is ONE of the following:

- Relapsed
- Stage IV disease

Product Name: Brand Afinitor, generic everolimus, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Renal cell cancer, Kidney Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Renal Angiomyolipoma with Tuberous Sclerosis Complex
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of renal angiomyolipoma and tuberous sclerosis complex (TSC), not requiring immediate surgery

Product Name: Brand Afinitor, generic everolimus, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Renal Angiomyolipoma with Tuberous Sclerosis Complex
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Subependymal Giant Cell Astrocytoma Associated with Tuberous Sclerosis Complex
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis (TS)

AND

2 - Patient is not a candidate for curative surgical resection

Product Name: Brand Afinitor, generic everolimus, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Subependymal Giant Cell Astrocytoma Associated with Tuberous Sclerosis Complex
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Waldenströms Macroglobulinemia or Lymphoplasmacytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

- Waldenströms macroglobulinemia
- Lymphoplasmacytic lymphoma

AND

2 - One of the following:

- Disease is non-responsive to primary treatment
- Disease is progressive
- Disease has relapsed

Product Name: Brand Afinitor, generic everolimus, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Waldenströms Macroglobulinemia or Lymphoplasmacytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - One of the following:

2.1 Disease is recurrent

OR

2.2 Disease is metastatic

AND

3 - One of the following:

3.1 Disease is hormone receptor positive (HR+) [i.e., estrogen-receptor-positive (ER+) or progesterone-receptor-positive (PR+)]

OR

3.2 BOTH of the following:

- Disease is hormone receptor negative (HR-)

- Disease has clinical characteristics that predict a HR+ tumor

AND

4 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

5 - One of the following:

5.1 Patient is a postmenopausal woman

OR

5.2 BOTH of the following:

- Patient is a premenopausal woman
- Patient is being treated with ovarian ablation/suppression

OR

5.3 Patient is male

AND

6 - One of the following:

6.1 Both of the following:

6.1.1 Used in combination with exemestane (generic Aromasin)

AND

6.1.2 One of the following:

6.1.2.1 Disease progressed while on or within 12 months of non-steroidal aromatase inhibitor [e.g., anastrozole (generic Arimidex), letrozole (generic Femara)] therapy

OR

6.1.2.2 Patient was treated with tamoxifen at any time, as confirmed by claims history or submission of medical records

OR

6.2 Used in combination with ONE of the following:

- Fulvestrant
- Tamoxifen

Product Name: Brand Afinitor, generic everolimus, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Hodgkin Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of classical Hodgkin lymphoma

AND

2 - ONE of the following:

- Disease is refractory
- Disease has relapsed

Product Name: Brand Afinitor, generic everolimus, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Hodgkin Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	PEComa (perivascular epitheliod cell tumor), recurrent angiomyolipoma, lymphangioleiomyomatosis, or gastrointestinal stromal tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of PEComa (perivascular epitheliod cell tumor)

OR

2 - Diagnosis of recurrent angiomyolipoma

OR

3 - Diagnosis of lymphangioleiomyomatosis

OR

4 - All of the following:

4.1 Diagnosis of Gastrointestinal Stromal Tumor (GIST)

AND

4.2 Disease has progressed after single agent therapy with ONE of the following:

- imatinib (generic Gleevec)
- sunitinib (generic Sutent)
- Stivarga (regorafenib)

AND

4.3 Used in combination with ONE of the following:

- imatinib (generic Gleevec)
- sunitinib (generic Sutent)
- Stivarga (regorafenib)

Product Name: Brand Afinitor, generic everolimus, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	PEComa (perivascular epitheliod cell tumor), recurrent angiomyolipoma, lymphangioleiomyomatosis, or gastrointestinal stromal tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Thymic Carcinoma or Thymoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

- Diagnosis of thymic carcinoma
- Diagnosis of thymoma

AND

2 - ONE of the following:

2.1 History of failure, contraindication, or intolerance to at least one prior first-line chemotherapy regimen

OR

2.2 Patient has extrathoracic metastatic disease

Product Name: Brand Afinitor, generic everolimus, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Thymic Carcinoma or Thymoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Follicular carcinoma, Hürthle cell carcinoma, or papillary carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Follicular carcinoma
- Hürthle cell carcinoma
- Papillary carcinoma

AND

2 - ONE of the following:

- Unresectable locoregional recurrent disease
- Persistent disease
- Metastatic disease

AND

3 - ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

AND

4 - Disease is refractory to radioactive iodine treatment

Product Name: Brand Afinitor, generic everolimus, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Follicular carcinoma, Hürthle cell carcinoma, or papillary carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Meningioma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of meningioma

AND

2 - Disease is recurrent or progressive

AND

3 - Surgery and/or radiation is not possible

AND

4 - Used in combination with bevacizumab (e.g., Avastin, Myasi)

Product Name: Brand Afinitor, generic everolimus, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Meningioma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Endometrial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of endometrial carcinoma

AND

2 - Used in combination with letrozole

Product Name: Brand Afinitor, generic everolimus, Brand Afinitor Disperz, generic everolimus TBSO

Diagnosis	Endometrial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Tuberous Sclerosis Complex associated Partial-Onset Seizures
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of tuberous sclerosis complex associated partial-onset seizures

AND

2 - Used as adjunctive therapy

Product Name: Brand Afinitor, generic everolimus, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Tuberous Sclerosis Complex associated Partial-Onset Seizures
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Osteosarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of osteosarcoma

AND

2 - Disease is ONE of the following:

- Relapsed
- Refractory
- Metastatic

AND

3 - Used in combination with Nexavar (sorafenib)

AND

4 - Not used as first-line therapy

Product Name: Brand Afinitor, generic everolimus, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Osteosarcoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following

- Rosai-Dorfman Disease
- Langerhans Cell Histiocytosis
- Erdheim-Chester Disease

Product Name: Brand Afinitor, generic everolimus, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Brand Afinitor, generic everolimus, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Afinitor therapy

Prior Authorization Guideline

GL-90690 Alecensa

Formulary

Formulary Note

Guideline Note:

Effective Date:	11/1/2021

1 . Criteria

Product Name: Alecensa	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of non-small cell lung cancer (NSCLC)	

AND

2 - Disease is one of the following:

- Metastatic
- Recurrent
- Advanced

AND

3 - Tumor is anaplastic lymphoma kinase (ALK)-positive

Product Name: Alecensa	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Alecensa therapy

Product Name: Alecensa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Alecensa will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Product Name: Alecensa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Alecensa therapy

2 . Revision History

Date	Notes
8/4/2021	Added advanced disease to criteria

Prior Authorization Guideline

GL-78361 Alinia

Formulary

Formulary Note

Guideline Note:

Effective Date:	2/1/2021

1 . Criteria

Product Name: Brand Alinia, generic nitazoxanide	
Diagnosis	Diarrhea caused by Giardia lamblia
Approval Length	3 Day(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of giardiasis	

AND

2 - History of failure, contraindication, or intolerance to metronidazole

Product Name: Brand Alinia, generic nitazoxanide	
Diagnosis	Diarrhea caused by Cryptosporidium parvum
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cryptosporidiosis

Prior Authorization Guideline

GL-89067 Alunbrig

Formulary

Formulary Note

Guideline Note:

Effective Date:	9/1/2021

1 . Criteria

Product Name: Alunbrig	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of non-small cell lung cancer (NSCLC)	

AND

2 - Disease is one of the following:

- Metastatic
- Recurrent
- Advanced

AND

3 - Tumor is anaplastic lymphoma kinase (ALK)-positive

Product Name: Alunbrig	
Diagnosis	Inflammatory Myofibroblastic Tumor (IMT)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of inflammatory myofibroblastic tumor (IMT) with ALK (anaplastic lymphoma kinase) translocation

Product Name: Alunbrig	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC), Inflammatory Myofibroblastic Tumor (IMT)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Alunbrig therapy

Product Name: Alunbrig	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Alunbrig	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Alunbrig therapy

Prior Authorization Guideline

GL-108605 Analgesic Agents Opioids

Formulary

Formulary Note

Guideline Note:

Effective Date:	8/1/2022

1 . Criteria

Product Name: Brand Butrans patch, generic morphine sulfate ER tablets (generic for MS Contin)	
Diagnosis	Long-Acting Opioids Preferred
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - ONE of the following:	

1.1 Catastrophic injury or cancer pain*

OR

1.2 For all other causes of pain, documentation of ALL of the following:

1.2.1 Treatment plan including ALL of the following:

- Risk assessment
- Substance abuse history
- Concurrent therapies

AND

1.2.2 Ohio Automated Rx Reporting System (OARRS) checked within 7 days prior to initiating long-acting therapy

AND

1.2.3 Documentation of pain and function scores at each visit

AND

1.2.4 Baseline urine drug test submitted and treatment plan includes requirements for random urine screens

AND

1.2.5 Opioid contract is in place and submitted with prior authorization request

AND

1.2.6 Documented failure of both non-opioid pharmacologic and non-pharmacologic treatments

AND

1.2.7 History of short-acting opioids for greater than or equal to 60 days

Notes	*NOTE: Catastrophic injury or cancer pain does not require additional documentation (documentation should be provided as part of the prior authorization form)

Product Name: Belbuca, Brand Hysingla ER, generic hydrocodone ER tablets, Brand Zohydro ER, generic hydrocodone ER capsules, Arymo ER, morphine sulfate ER capsules (generic for Kadian), morphine sulfate ER bead caps, Oxycontin, Brand Oxycodone ER tablets, Xtampza, Brand Conzip, brand Tramadol ER 24HR biphasic capsules, generic tramadol ER tablets, generic tramadol ER biphasic release tablets, generic oxymorphone ER tablets, generic hydromorphone ER deter, Nucynta ER, generic methadone tablets, Brand Methadose, generic methadone concentrate, generic methadone intensol, generic methadone solution, generic buprenorphine patch, Brand Duragesic, generic fentanyl patch, Brand MS Contin

Diagnosis	Long-Acting Opioids Non-Preferred
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient has had an inadequate clinical response to a 7 day trial of one preferred product*

OR

1.2 Patient cannot be changed to a preferred medication due to ONE of the following:

1.2.1 Patient has an allergy to TWO unrelated preferred medications

OR

1.2.2 Patient has a contraindication to, or drug-to-drug interaction with, preferred medications

OR

1.2.3 Patient has a history of unacceptable/toxic side effects to preferred medications

AND

2 - If applicable, the patient must have failed the generic product (if covered by the state) before brand is authorized

AND

3 - ONE of the following:

3.1 Catastrophic injury or cancer pain

OR

3.2 For all other causes of pain, documentation of ALL of the following:**

3.2.1 Treatment plan including ALL of the following:

- Risk assessment
- Substance abuse history
- Concurrent therapies

AND

3.2.2 Ohio Automated Rx Reporting System (OARRS) checked within 7 days prior to initiating long-acting therapy

AND

3.2.3 Documentation of pain and function scores at each visit

AND

3.2.4 Baseline urine drug test submitted and treatment plan includes requirements for random urine screens

AND

3.2.5 Opioid contract is in place and submitted with prior authorization request

AND

3.2.6 Documented failure of both non-opioid pharmacologic and non-pharmacologic treatments

AND

3.2.7 History of short-acting opioids for greater than or equal to 60 days

Notes	*NOTE: PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP **NOTE: Catastrophic injury or cancer pain does not require additional documentation

Product Name: Belbuca, Brand Hysingla ER, generic hydrocodone ER tablets, Brand Zohydro ER, generic hydrocodone ER capsules, Arymo ER, morphine sulfate ER capsules (generic for Kadian), morphine sulfate ER bead caps, Oxycontin, Brand Oxycodone ER tablets, Xtampza, Brand Conzip, Brand Tramadol ER biphasic capsules, generic tramadol ER tablets, generic tramadol ER biphasic release tablets, generic oxymorphone ER tablets, generic hydromorphone ER deter, Nucynta ER, generic methadone tablets, Brand Methadose, generic methadone concentrate, generic methadone intensol, generic methadone solution, Brand Butrans patch, generic buprenorphine patch, Brand Duragesic, generic fentanyl patch, Brand MS Contin, generic morphine sulfate ER tablets (generic for MS Contin)	
Diagnosis	Long-Acting Opioids Preferred, Long-Acting Opioids Non-Preferred
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Current treatment plan

AND

2 - Demonstrated adherence to treatment plan through progress notes including pain and function scores and random urine screens results reviewed and concerns addressed, no serious adverse outcomes observed

Product Name: Belbuca, Brand Hysingla ER, generic hydrocodone ER tablets, Brand Zohydro ER, generic hydrocodone ER capsules, Arymo ER, morphine sulfate ER capsules (generic for Kadian), morphine sulfate ER bead caps, Oxycontin, Brand Oxycodone ER tablets, Xtampza, Brand Conzip, Brand Tramadol ER biphasic capsules, generic tramadol ER tablets, generic tramadol ER biphasic release tablets, generic oxymorphone ER tablets, generic hydromorphone ER deter, Nucynta ER, generic methadone tablets, Brand Methadose, generic methadone concentrate, generic methadone intensol, generic methadone solution, Brand Butrans patch, generic buprenorphine patch, Brand Duragesic, generic fentanyl patch, Brand MS Contin, generic morphine sulfate ER tablets (generic for MS Contin)	
Diagnosis	Dose Escalation Requests for Long Acting Opioids to exceed Cumulative 90 MME Limit*
Guideline Type	Quantity Limit

Approval Criteria

1 - Dose escalation request to exceed cumulative 90 morphine milligram equivalents (MME) limit requires ALL of the following:*

1.1 Prescriber indicates escalation of dose is likely to result in improved function and pain control

AND

1.2 Cumulative dose greater than 100 morphine equivalent dose (MED) is made in consultation with pain specialist or anesthesiologist*

Notes	*NOTE: Catastrophic injury, cancer pain, palliative care, end-of-life/hospice care, sickle cell, severe burn, traumatic crushing of tissue, amputation are exempt from MME limits and the authorization should be entered for an MME of 9999 so as to prevent future disruptions in therapy

	if the patient's dose is increased. For all other conditions, if the patien t has been established on the requested MME dose for at least 30 day s and does not meet the medical necessity authorization criteria requir ements, a denial should be issued and a maximum 60-day authorizati on may be authorized one time for the requested MME dose. NOTE: Authorization length for initial request is 3 months (90 days); the autho rization length for renewal requests is 6 months (180 days).

Product Name: Levorphanol tablets, meperidine tablets, Oxaydo 7.5 mg, oxymorphone immediate release tablets, Nucynta IR, Apadaz, Benzhydrocodone/acetaminophen, hydrocodone/ibuprofen tablets, hydrocodone 7.5-300 mg tablets, hydrocodone 10-300 mg tablets, Brand Xodol, generic hydrocodone 5-300 mg tablets, Prolate, pentazocine-naloxone tablets, carisoprodol-aspirin-codeine tablets, meperidine oral solution, hydrocodone-acetaminophen 10-325 mg/15 m oral solution, Brand Trezix, generic acetaminophen-caffeine-dihydrocodeine, Brand Dilaudid tablets, Brand Roxicodone tablets, Brand Percocet, Nalocet, Oxycodone-acetaminophen 2.5-300 mg, 5-300 mg, 7.5-300mg, 10-300 mg tablets and 10-300 mg/5 ml solution, Brand Ultracet, Brand Ultram, Brand Dilaudid 1 mg/ml, Brand Lortab elixir, Brand Fioricet/codeine, generic butalbital-acetaminophen-caffeine-codeine 50-300-40-30 mg capsule, Qdolo, Tramadol oral soln, Roxybond	
Diagnosis	Short-Acting Opioids Non-Preferred
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following for a non-preferred product*:

1.1 Patient has had an inadequate clinical response to a 7 day trial of one preferred product*

OR

1.2 Patient cannot be changed to a preferred medication due to ONE of the following:

1.2.1 Patient has an allergy to TWO unrelated preferred medications

OR

1.2.2 Patient has a contraindication to, or drug-to-drug interaction with, preferred medications

OR

1.2.3 Patient has a history of unacceptable/toxic side effects to preferred medications

AND

2 - If applicable, the patient must have failed the generic product (if covered by the state) before brand is authorized

Notes	*NOTE: PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Levorphanol tablets, meperidine tablets, Oxaydo, oxymorphone immediate release tablets, Nucynta IR, Apadaz, Benzhydrocodone/acetaminophen, hydrocodone/ibuprofen tablets, hydrocodone 7.5-300 mg tablets, hydrocodone 10-300 mg tablets, Brand Xodol, generic hydrocodone 5-300 mg tablets, Prolate, pentazocine-naloxone tablets, carisoprodol-aspirin-codeine tablets, meperidine oral solution, Brand Trezix, generic acetaminophen-caffeine-dihydrocodeine, codeine tablets, Brand Dilaudid tablets, generic hydromorphone tablets, morphine sulfate immediate release tablets, Brand Roxicodone tablets, generic oxycodone immediate release tablets, oxycodone immediate release capsule, acetaminophen-codeine tablets, hydrocodone 5-325 mg tablets, hydrocodone 10-325 mg tablets, hydrocodone 7.5-325 mg tablets, Brand Percocet, Endocet, Nalocet, Oxycodone-acetaminophen tablets, generic oxycodone-acetaminophen tablets, Oxycodone-acetaminophen soln, Brand Ultracet, generic tramadol-acetaminophen, Brand Ultram, generic tramadol, Brand Dilaudid 1 mg/ml, generic hydromorphone 1 mg/ml, morphine sulfate oral solution, oxycodone concentrate, oxycodone solution, acetaminophen-codeine solution, Brand Lortab elixir, hydrocodone-acetaminophen oral solution, butorphanol nasal solution, Brand Fioricet/codeine, generic butalbital-acetaminophen-caffeine-codeine capsule, Ascomp/codeine, generic butalbital-aspirin-caffeine-codeine, morphine suppositories, hydromorphone suppositories, generic oxycodone-aspirin, Qdolo, Tramadol oral soln, Roxybond

Diagnosis	Dose Escalation Requests for Short Acting Opioids to Exceed 30 MME per Product or Cumulative 90 MME Limit
Approval Length	180 Day(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - Requests exceeding 30 morphine milligram equivalents (MME) per product and/or cumulative 90 MME limit per prescription requires ALL of the following:*

1.1 Prescriber indicates the requested dose is likely to result in improved function and pain control

AND

1.2 Cumulative dose greater than 100 morphine equivalent dose (MED) is made in consultation with pain specialist or anesthesiologist

Notes	*NOTE: Catastrophic injury, cancer pain, palliative care, end-of-life/hospice care, sickle cell, severe burn, traumatic crushing of tissue, amputation, major orthopedic surgery are exempt from MME and MDD limits and 7 day supply limit, and the authorization should be entered for an MME of 9999 and MDD of 999 so as to prevent future disruptions in therapy if the patient's dose is increased. For all other conditions, if the patient has been established on the requested MME dose for at least 30 days and does not meet the medical necessity authorization criteria requirements, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested MME dose.

Product Name: Levorphanol tablets, meperidine tablets, Oxaydo, oxymorphone immediate release tablets, Nucynta IR, Apadaz, Benzhydrocodone/acetaminophen, hydrocodone/ibuprofen tablets, hydrocodone 7.5-300 mg tablets, hydrocodone 10-300 mg tablets, Brand Xodol, generic hydrocodone 5-300 mg tablets, Prolate, pentazocine-naloxone tablets, carisoprodol-aspirin-codeine tablets, meperidine oral solution, Brand Trezix, generic acetaminophen-caffeine-dihydrocodeine, codeine tablets, Brand Dilaudid tablets, generic hydromorphone tablets, morphine sulfate immediate release tablets, Brand Roxicodone tablets, generic oxycodone immediate release tablets, oxycodone immediate release capsule, acetaminophen-codeine tablets, hydrocodone 5-325 mg tablets, hydrocodone 10-325 mg tablets, hydrocodone 7.5-325 mg tablets, Brand Percocet, Endocet, Nalocet, Oxycodone-acetaminophen tablets, generic oxycodone-acetaminophen tablets, Oxycodone-acetaminophen soln, Brand Ultracet, generic tramadol-acetaminophen, Brand Ultram, generic tramadol, Brand Dilaudid 1 mg/ml, generic hydromorphone 1 mg/ml, morphine sulfate oral solution, oxycodone concentrate, oxycodone solution, acetaminophen-codeine solution, Brand Lortab elixir, hydrocodone-acetaminophen oral solution, butorphanol nasal solution, Brand Fioricet/codeine, generic butalbital-acetaminophen-caffeine-codeine capsule, Ascomp/codeine, generic butalbital-aspirin-caffeine-codeine, morphine suppositories, hydromorphone suppositories, generic oxycodone-aspirin. Qdolo, Tramadol oral soln, Roxybond

Diagnosis	New Start*
Approval Length	90 Days**
Guideline Type	Quantity Limit

Approval Criteria

1 - Requests for a “new start” to exceed a 7 day supply limit require ALL of the following:*

1.1 Patient had a trial and failure of non-pharmacologic treatments and/or non-opioid analgesics are ineffective or contraindicated

AND

1.2 Diagnosis code is submitted and should be for somatic type pain

AND

1.3 Provider attestation that the benefits and risks of opioid therapy have been discussed with patient

AND

1.4 Prescriber attestation that the Ohio Automated Rx Reporting System (OARRS) has been checked

OR

2 - The patient is receiving short-acting opioids to treat one of the following:

- Active cancer treatment
- Palliative care
- End-of-life/hospice care
- Sickle cell
- Severe burn
- Traumatic crushing of tissue
- Amputation
- Major orthopedic surgery

OR

3 - There is attestation that patient is not opioid naïve based on ONE of the following:

- Patient is newly eligible for Medicaid and there is no prior claims data
- Patient was on a higher dose in the hospital

Notes	*NOTE: “New start” is defined as having less than a 1-day supply of o pioids in the previous 90 days **NOTE: Length of authorization is UP TO 90 days, depending on the indication, previous member utilization, and requested length of therapy (could be more restrictive)

Product Name: Brand Actiq, generic fentanyl lozenge, Fentora, Fentanyl citrate buccal tablets, Subsys	
Diagnosis	Transmucosal Fentanyl
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of cancer pain

AND

2 - Prescription is from oncologist or pain specialist

AND

3 - Patient is concurrently taking a long-acting opioid at therapeutic dose (ANY of the following for greater than or equal to 1 week without adequate pain relief):

- Greater than or equal to 60 milligrams (mg) oral morphine/day
- Greater than or equal to 25 micrograms (mcg)/hour transdermal fentanyl
- Greater than or equal to 30 mg oral oxycodone/day
- Greater than or equal to 8 mg oral hydromorphone/day
- Greater than or equal to 25 mg oral oxymorphone/day
- Equianalgesic dose of another opioid

AND

4 - Dose is less than or equal to 4 units per day

2 . Revision History

Date	Notes
6/24/2022	Updated GPI's and product names

Prior Authorization Guideline

GL-107389 Analgesic Agents, NSAIDs

Formulary

Formulary Note

Guideline Note:

Effective Date:	7/1/2022

1 . Criteria

Product Name: brand Zorvolex, brand Lofena, brand Cataflam, brand Arthrotec, generic diclofenac sodium/misoprostol, brand Flector, generic diclofenac patch, brand Voltaren gel, brand Aspercreme 1% gel, brand Celebrex, Diclotrex, Diclotrex II, brand Nalfon tabs and caps, Fenortho, generic fenoprofen caps, brand ibuprofen caps and tab (Advil caps and tabs, Motrin IB caps and tabs, Advil liquid-gels minis, Advil migraine, Advil Cold & Sinus, Advil PM, Motrin PM), brand ibuprofen chew tabs (Advil junior strength, Motrin children's), brand ibuprofen susp (Motrin infant drops, Infant Advil, Hyvee ibuprofen children's, Children's Advil, Children's Motrin), brand Duexis, generic ibuprofen/famotidine, Sprix, generic ketorolac nasal spray, ketoprofen, Licart patch, Brand Vivlodex, generic meloxicam caps, brand Mobic, brand Naprosyn tabs, brand EC-Naprosyn, generic Naproxen EC, brand Naproxen caps and tabs (Aleve, Pamprin all day maximum strength, Aleve Arthritis, Mediproxen, Anaprox DS), brand Naprelan, generic naproxen ER/CR tab, brand Vimovo, generic naproxen/esomeprazole, brand Pennsaid 2% soln, diclofenac soln, brand Relafen, Relafen DS, brand Zipsor, brand Lodine, brand Tivorbex, brand Daypro, brand Feldene, brand Naprosyn susp, Elyxyb

Approval Length	For H. pylori: 30 days; If transdermal/topical product: 90 days; For all other treatments: 365 days
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following*:

1.1 History of a 30 day trial and failure with TWO preferred medications

OR

1.2 Allergy to ALL preferred medications

OR

1.3 Contraindication to or drug-to-drug interaction with preferred medications

OR

1.4 History of unacceptable/toxic side effects to preferred medications

Notes	*OH PDL - https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: generic naproxen susp	
Diagnosis	Requests for Patients OVER 12 years of age
Approval Length	12 month(s)
Guideline Type	Age Edit

Approval Criteria

1 - ONE of the following*:

1.1 History of a 30 day trial and failure with TWO preferred medications

OR **1.2** Allergy to ALL preferred medications **OR** **1.3** Contraindication to or drug-to-drug interaction with preferred medications **OR** **1.4** History of unacceptable/toxic side effects to preferred medications

Notes	*OH PDL - https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
5/20/2022	Added Elyxyb. Updated GPI list.

Prior Authorization Guideline

GL-98990 Analgesic Agents- Gout

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: Brand Uloric, generic febuxostat	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following:

1.1 Allergy to preferred medications*

OR

1.2 Contraindication to or drug-to-drug interaction with preferred medications*

OR

1.3 History of unacceptable/toxic side effects to preferred medications*

AND

2 - Patient has ONE of the following:

2.1 History of a 30 day trial of maximum allopurinol dose

OR

2.2 Intolerance/contraindication to allopurinol

Notes	* PDL Link - https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: generic colchicine, Brand Mitigare, Brand Colcrys	
Diagnosis	Familial Mediterranean Fever (FMF)
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of Familial Mediterranean Fever (FMF)

AND

2 - If the request is for colchicine capsules the patient has a history of trial and failure with colchicine tablets

AND

3 - If the request is for a non-preferred medication ONE of the following:

- Allergy to preferred medications*
- Contraindication to or drug-to-drug interaction with preferred medications*
- History of unacceptable/toxic side effects to preferred medications*

AND

4 - Quantity prescribed does not exceed 120 units colchicine per 30 days

Notes	* PDL Link - https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: generic colchicine, Brand Mitigare, Brand Colcrys	
Diagnosis	Acute Gout Pain
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has had a trial of ONE of the following in the last 30 days:

- NSAID (i.e. indomethacin, naproxen, ibuprofen, sulindac, ketoprofen)
- Oral corticosteroid

AND

2 - If the request is for colchicine capsules the patient has a history of trial and failure with colchicine tablets

AND

3 - If the request is for a non-preferred medication ONE of the following:

- Allergy to preferred medications*
- Contraindication to or drug-to-drug interaction with preferred medications*
- History of unacceptable/toxic side effects to preferred medications*

AND

4 - Quantity prescribed does not exceed 6 units colchicine per prescription claim

Notes	* PDL Link - https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: generic colchicine, Brand Mitigare, Brand Colcrys	
Diagnosis	Chronic Gout Pain
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has had a trial on a xanthine oxidase inhibitor

AND

2 - Patient has had a trial of ONE of the following in the last 30 days:

- NSAID (i.e. indomethacin, naproxen, ibuprofen, sulindac, ketoprofen)
- Oral corticosteroid

AND

3 - If the request is for colchicine capsules the patient has a history of trial and failure with colchicine tablets

AND

4 - If the request is for a non-preferred medication ONE of the following:

- Allergy to preferred medications*
- Contraindication to or drug-to-drug interaction with preferred medications*
- History of unacceptable/toxic side effects to preferred medications*

AND

5 - Quantity prescribed does not exceed 60 units colchicine per 30 days

Notes	* PDL Link - https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Gloperba	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following:

1.1 Allergy to preferred medications*

OR

1.2 Contraindication to or drug-to-drug interaction with preferred medications*

OR

1.3 History of unacceptable/toxic side effects to preferred medications*

AND

2 - Patient is unable to swallow colchicine tablets or capsules

AND

3 - Patient is using Gloperba for the prevention of gout flares

AND

4 - Patient has trial of ONE of the following in the last 30 days:

- NSAID (Non-steroidal anti-inflammatory drug) (i.e., indomethacin, naproxen, ibuprofen, sulindac, ketoprofen)
- Oral corticosteroid

Notes	* PDL Link - https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Brand Zyloprim	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following:

1.1 Allergy to preferred medications*

OR

1.2 Contraindication to or drug-to-drug interaction with preferred medications*

OR **1.3** History of unacceptable/toxic side effects to preferred medications*
Notes | * PDL Link - https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: probenecid/colchicine	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - History of trial of ONE of the following within the last 30 days: • NSAID (i.e., indomethacin, naproxen, ibuprofen, sulindac, ketoprofen) • Oral corticosteroid	
Notes	* PDL Link - https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
12/1/2021	Update

Prior Authorization Guideline

GL-108032 Anthelmintics

Formulary

Formulary Note

Guideline Note:

Effective Date:	8/1/2022

1 . Criteria

Product Name: Generic albendazole,Emverm	
Diagnosis	Enterobius vermicularis (pinworm)
Approval Length	1 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Enterobius vermicularis (pinworm)	

AND

2 - ONE of the following:

2.1 Failure of over-the-counter pyrantel pamoate confirmed by claims history or submitted medical records

OR

2.2 History of intolerance or contraindication to over-the-counter pyrantel pamoate (please specify intolerance or contraindication)

Product Name: Generic albendazole	
Diagnosis	Taenia solium (Neurocysticercosis)
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Neurocysticercosis

Product Name: Generic albendazole,Emverm	
Diagnosis	Echinococcosis (Tapeworm)
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Hydatid Disease [Echinococcosis (Tapeworm)]

Product Name: Emverm	
Diagnosis	Ancylostoma/Necatoriasis (Hookworm)
Approval Length	1 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Ancylostoma/Necatoriasis (Hookworm)

Product Name: Generic albendazole	
Diagnosis	Ancylostoma/Necatoriasis (Hookworm)
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Ancylostoma/Necatoriasis (Hookworm)

Product Name: Generic albendazole,Emverm	
Diagnosis	Ascariasis (Roundworm)
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Ascariasis (Roundworm)

Product Name: Generic albendazole,Emverm	
Diagnosis	Toxocariasis (Roundworm)
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Toxocariasis (Roundworm)

Product Name: Generic albendazole,Emverm	
Diagnosis	Trichinellosis
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Trichinellosis

Product Name: Generic albendazole, Emverm	
Diagnosis	Trichuriasis (Whipworm)
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Trichuriasis (Whipworm)

Product Name: Generic albendazole,Emverm	
Diagnosis	Capillariasis
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Capillariasis

Product Name: Generic albendazole,Emverm	
Diagnosis	Baylisascaris
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Baylisascaris

Product Name: Generic albendazole	
Diagnosis	Clonorchiasis (Liver flukes)
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Clonorchiasis (Liver flukes)

Product Name: Generic albendazole	
Diagnosis	Gnathostomiasis
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Gnathostomiasis

Product Name: Generic albendazole	
Diagnosis	Strongyloidiasis
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Strongyloidiasis

Product Name: Generic albendazole	
Diagnosis	Loiasis
Approval Length	1 month(s)

Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Loiasis	

Product Name: Generic albendazole	
Diagnosis	Opisthorchis
Approval Length	1 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Opisthorchis	

2 . Revision History

Date	Notes
6/9/2022	Changed Ancylostoma/Necatoriasis authorization to six months per CDC recommendation for Albenza. Formatting changes. Updated tria l/failure language.

Prior Authorization Guideline

GL-66033 Anthelmintics

Formulary

Formulary Note

Guideline Note:

Effective Date:	7/1/2020

1 . Criteria

Product Name: Brand Albenza, generic albendazole, Emverm	
Diagnosis	Enterobius vermicularis (pinworm)
Approval Length	1 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Enterobius vermicularis (pinworm)	

AND

2 - History of failure, contraindication or intolerance to over-the-counter pyrantel pamoate

Product Name: Brand Albenza, generic albendazole	
Diagnosis	Taenia solium (Neurocysticercosis)
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Neurocysticercosis

Product Name: Brand Albenza, generic albendazole, Emverm	
Diagnosis	Echinococcosis (Tapeworm)
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Hydatid Disease [Echinococcosis (Tapeworm)]

Product Name: Brand Albenza, generic albendazole, Emverm	
Diagnosis	Ancylostoma/Necatoriasis (Hookworm)
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Ancylostoma/Necatoriasis (Hookworm)

Product Name: Brand Albenza, generic albendazole, Emverm	
Diagnosis	Ascariasis (Roundworm)
Approval Length	1 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Ascariasis (Roundworm)	

Product Name: Brand Albenza, generic albendazole, Emverm	
Diagnosis	Toxocariasis (Roundworm)
Approval Length	1 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Toxocariasis (Roundworm)	

Product Name: Brand Albenza, generic albendazole, Emverm	
Diagnosis	Trichinellosis
Approval Length	1 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Trichinellosis	

Product Name: Brand Albenza, generic albendazole, Emverm	
Diagnosis	Trichuriasis (Whipworm)
Approval Length	1 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of Trichuriasis (Whipworm)

Product Name: Brand Albenza, generic albendazole, Emverm	
Diagnosis	Capillariasis
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Capillariasis

Product Name: Brand Albenza, generic albendazole, Emverm	
Diagnosis	Baylisascaris
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Baylisascaris

Product Name: Brand Albenza, generic albendazole	
Diagnosis	Clonorchiasis (Liver flukes)
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Clonorchiasis (Liver flukes)

Product Name: Brand Albenza, generic albendazole	
Diagnosis	Gnathostomiasis
Approval Length	1 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Gnathostomiasis

Product Name: Brand Albenza, generic albendazole	
Diagnosis	Strongyloidiasis
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Strongyloidiasis

Product Name: Brand Albenza, generic albendazole	
Diagnosis	Loiasis
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Loiasis

Product Name: Brand Albenza, generic albendazole	
Diagnosis	Opisthorchis
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Opisthorchis

2 . Revision History

Date	Notes
5/5/2020	Annual review. Added Albenza for Loa loa, Opisthorchis per CDC gui delines. Removed Emverm and Vermox for Mansonella perstans.

Prior Authorization Guideline

GL-108065 Arcalyst

Formulary

Formulary Note

Guideline Note:

Effective Date:	8/1/2022

1 . Criteria

Product Name: Arcalyst	
Diagnosis	Cryopyrin-Associated Periodic Syndromes (CAPS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS)

Product Name: Arcalyst	
Diagnosis	Deficiency of Interleukin-1 Receptor Antagonist (DIRA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

AND

2 - Disease is in remission (e.g., diary score of less than 0.5 [reflecting no fever, skin rash and bone pain], acute phase reactants [less than 0.5 mg/dL CRP (milligrams per deciliter C-Reactive protein)], absence of objective skin rash, no radiological evidence of active bone lesions)

Product Name: Arcalyst	
Diagnosis	Pericarditis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent pericarditis (RP)

Product Name: Arcalyst	
Diagnosis	Cryopyrin-Associated Periodic Syndromes (CAPS), Deficiency of Interleukin-1 Receptor Antagonist (DIRA), Pericarditis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Documentation of positive clinical response to Arcalyst therapy

2 . Revision History

Date	Notes
6/10/2022	Updated formatting of CAPS criteria and spelled out < in DIRA criteria.

Prior Authorization Guideline

GL-95974 Ayvakit

Formulary

Formulary Note

Guideline Note:

Effective Date:	12/1/2021

1 . Criteria

Product Name: Ayvakit	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of gastrointestinal stromal tumor (GIST)	

AND

2 - ONE of the following:

2.1 Used as single agent for continued treatment for limited progression

OR

2.2 ALL of the following:

2.2.1 Disease is ONE of the following:

- Unresectable
- Metastatic
- Recurrent
- Persistent microscopic or gross residual disease
- Residual disease with significant morbidity

AND

2.2.2 ONE of the following:

2.2.2.1 Presence of platelet-derived growth factor receptor alpha (PDGFRA) exon 18 D842v mutation

OR

2.2.2.2 BOTH of the following:

- Presence of a non-D842V, PDGFRA exon 18 mutation
- History of failure, contraindication, or intolerance to imatinib (Gleevec)

Product Name: Ayvakit	
Diagnosis	Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of myeloid/lymphoid neoplasms with eosinophilia

AND

2 - Presence of FIP1L1-PDGFRA (platelet-derived growth factor receptor alpha) rearrangement

AND

3 - Presence of a PDGFRA D842V mutation

Product Name: Ayvakit	
Diagnosis	Systemic Mastocytosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Advanced systemic mastocytosis
- Aggressive systemic mastocytosis
- Systemic mastocytosis with an associated hematological neoplasm
- Mast cell leukemia

AND

2 - Platelet count is greater than 50 x 10^9/L

Product Name: Ayvakit

Diagnosis	Gastrointestinal Stromal Tumor (GIST), Myeloid/Lymphoid Neoplasms, Systemic Mastocytosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Ayvakit therapy

Product Name: Ayvakit	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Ayvakit will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Ayvakit	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Ayvakit therapy

2 . Revision History

Date	Notes
10/4/2021	Updated GPI's. Added criteria for systemic mastocytosis according to label and NCCN recommendations. Updated all other criteria other than NCCN.

Prior Authorization Guideline

GL-56529 Balversa

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2020
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Balversa	
Diagnosis	Urothelial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of urothelial carcinoma

AND

2 - ONE of the following:

- Locally advanced
- Metastatic

AND

3 - Patient has fibroblast growth factor receptor (FGFR) 3 or FGFR2 genetic alterations

AND

4 - Patient has progressed during or following at least one line of prior chemotherapy or immunotherapy, or within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy

Product Name: Balversa	
Diagnosis	Urothelial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Balversa therapy

Product Name: Balversa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Use supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Balversa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Balversa therapy

2 . Revision History

Date	Notes
11/6/2019	New Guideline.

Prior Authorization Guideline

GL-106385 Benlysta

Formulary

Formulary Note

Guideline Note:

Effective Date:	7/1/2022

1 . Criteria

Product Name: Benlysta SQ	
Diagnosis	Systemic Lupus Erythematosus
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of systemic lupus erythematosus

AND

2 - Laboratory testing has documented the presence of autoantibodies [e.g., ANA, Anti-dsDNA, Anti-Sm, Anti-Ro/SSA, Anti-La/SSB]

AND

3 - Patient is currently receiving standard immunosuppressive therapy [e.g., hydroxychloroquine, chloroquine, prednisone, azathioprine, methotrexate]

AND

4 - Patient does NOT have severe active central nervous system lupus

AND

5 - Patient is NOT receiving Benlysta in combination with any of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Kineret (anakinra)]
- Lupkynis (voclosporin)
- Saphnelo (anifrolumab-fnia)

Product Name: Benlysta SQ	
Diagnosis	Active Lupus Nephritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active lupus nephritis

AND

2 - Patient is currently receiving standard immunosuppressive therapy for systemic lupus erythematosus [e.g., hydroxychloroquine, chloroquine, prednisone, azathioprine, methotrexate]

AND

3 - Patient does NOT have severe active central nervous system lupus

AND

4 - Patient is NOT receiving Benlysta in combination with any of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Kineret (anakinra)]
- Lupkynis (voclosporin)
- Saphnelo (anifrolumab-fnia)

Product Name: Benlysta SQ	
Diagnosis	Systemic Lupus Erythematosus, Active Lupus Nephritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Benlysta therapy

AND

2 - Patient is NOT receiving Benlysta in combination with any of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Kineret (anakinra)]
- Lupkynis (voclosporin)
- Saphnelo (anifrolumab-fnia)

Prior Authorization Guideline

GL-62858 Benznidazole

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Benznidazole	
Approval Length	60 Day(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Chagas disease (American trypanosomiasis) due to Trypanosoma cruzi	

2 . Revision History

Date	Notes
3/4/2020	New Program

Prior Authorization Guideline

GL-62850 Biltricide

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Brand Biltricide, generic praziquantel	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

- Infections due to schistosoma
- Infections due to the liver trematodes (flukes), Clonorchis sinensis/Opisthorchis viverrini (i.e., clonorchiasis or opisthorchiasis)

2 . Revision History

Date	Notes
3/4/2020	New Program

Prior Authorization Guideline

GL-98981 Blood Formation, Coagulation, and Thrombosis Agents - Colony Stimulating Factors

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: Fulphila, Leukine, Neupogen, Nivestym, Zarxio, Granix, Udenyca, Neulasta, Neulasta Onpro, Ziextenzo, Nyvepria	
Guideline Type	Prior Authorization

Approval Criteria

1 - Requested medication must be used for an approved FDA (Food and Drug Administration) indication

AND

2 - If the request is non-preferred*, one of the following: **2.1** The patient cannot be changed to a preferred medication* due to ONE of the following acceptable reasons: • Allergy to preferred medications • Contraindication to all preferred medications • History of unacceptable/toxic side effects to preferred medications **OR** **2.2** Patient has failed therapeutic trials of 14 days with one preferred medication*

Notes	Approval duration is dependent on diagnosis, up to 30 days or duration of chemotherapy regimen *PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
11/29/2021	Updated preferred trial

Prior Authorization Guideline

GL-98980 Blood Formation, Coagulation, and Thrombosis Agents- Hematopoietic Agents

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: Aranesp, Mircera, Procrit, Epogen, Retacrit	
Approval Length	See chart in Background for duration
Guideline Type	Prior Authorization
Approval Criteria **1** - Requested medication is being used for an approved FDA (Food and Drug Administration) indication	

AND

2 - If the requested medication is non-preferred, ONE of the following

2.1 The patient cannot be changed to a preferred* medication due to ONE of the following acceptable reasons

- Allergy to preferred medications
- Contraindication to all preferred medications
- History of unacceptable/toxic side effects to preferred medications

OR

2.2 Patient has failed a therapeutic trial of 14 days with one preferred medication

Notes	*PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Background

Benefit/Coverage/Program Information

Approval durations

Approval of epoetin alfa or darbepoetin	
Diagnosis	**Approval Length**
Anemia due to chronic renal failure (regardless of dialysis)	12 months
Chemotherapy-induced anemia	90 days
Anemia in myelodysplastic syndrome	180 days
All other diagnosis	12 months

Approval of epoetin alfa only (not darbepoetin)	
Diagnosis	**Approval Length**

Autologous blood donation, patient will require blood transfusions	30 days
Anemia of prematurity, age <=6 months	42 days
Anemia associated with chronic inflammatory disorders (e.g., rheumatoid arthritis	180 days
Anemia associated with ribavirin combination therapy in hepatitis C infected patient	180 days
Anemia in zidovudine-treated HIV-infected patients	180 days
All other diagnosis	12 months

3 . Revision History

Date	Notes
11/30/2021	Deleted inactive GPI; Added specific approval durations based on di agnosis.

Prior Authorization Guideline

GL-98980 Blood Formation, Coagulation, and Thrombosis Agents- Hematopoietic Agents

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: Aranesp, Mircera, Procrit, Epogen, Retacrit	
Approval Length	See chart in Background for duration
Guideline Type	Prior Authorization

Approval Criteria

1 - Requested medication is being used for an approved FDA (Food and Drug Administration) indication

AND

2 - If the requested medication is non-preferred, ONE of the following

2.1 The patient cannot be changed to a preferred* medication due to ONE of the following acceptable reasons

- Allergy to preferred medications
- Contraindication to all preferred medications
- History of unacceptable/toxic side effects to preferred medications

OR

2.2 Patient has failed a therapeutic trial of 14 days with one preferred medication

Notes	*PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Background

Benefit/Coverage/Program Information

Approval durations

Approval of epoetin alfa or darbepoetin	
Diagnosis	**Approval Length**
Anemia due to chronic renal failure (regardless of dialysis)	12 months
Chemotherapy-induced anemia	90 days
Anemia in myelodysplastic syndrome	180 days
All other diagnosis	12 months

Approval of epoetin alfa only (not darbepoetin)	
Diagnosis	**Approval Length**
Autologous blood donation, patient will require blood transfusions	30 days
Anemia of prematurity, age <=6 months	42 days

Anemia associated with chronic inflammatory disorders (e.g., rheumatoid arthritis	180 days
Anemia associated with ribavirin combination therapy in hepatitis C infected patient	180 days
Anemia in zidovudine-treated HIV-infected patients	180 days
All other diagnosis	12 months

3 . Revision History

Date	Notes
11/30/2021	Deleted inactive GPI; Added specific approval durations based on di agnosis.

Prior Authorization Guideline

GL-56663 Blood Formation, Coagulation, and Thrombosis Agents- Heparin-Related Preparations

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2020

1 . Criteria

Product Name: brand Arixtra, generic fondaparinux, brand Fragmin	
Diagnosis	Patients With Cancer
Approval Length	6 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has history of failed therapeutic trials of 14 days with preferred medications*	

OR

2 - Patient has ONE of the following acceptable reasons the patient cannot be changed to the preferred medications:

- Allergy to preferred medications
- Contraindication to preferred medications
- History of unacceptable or toxic side effects to preferred medications

Notes	*Note: PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: brand Arixtra, generic fondaparinux, brand Fragmin	
Diagnosis	Pregnant Women
Approval Length	10 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has history of failed therapeutic trials of 14 days with preferred medications*

OR

2 - Patient has ONE of the following acceptable reasons the patient cannot be changed to the preferred medications:

- Allergy to preferred medications
- Contraindication to preferred medications
- History of unacceptable or toxic side effects to preferred medications

Notes	*Note: PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: brand Arixtra, generic fondaparinux, brand Fragmin	
Diagnosis	Patients Unable To Take Warfarin

Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has history of failed therapeutic trials of 14 days with preferred medications*

OR

2 - Patient has ONE of the following acceptable reasons the patient cannot be changed to the preferred medications:

- Allergy to preferred medications
- Contraindication to preferred medications
- History of unacceptable or toxic side effects to preferred medications

Notes	*Note: PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: brand Arixtra, generic fondaparinux, brand Fragmin	
Diagnosis	All Other Indications
Approval Length	35 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has history of failed therapeutic trials of 14 days with preferred medications*

OR

2 - Patient has ONE of the following acceptable reasons the patient cannot be changed to the preferred medications:

- Allergy to preferred medications
- Contraindication to preferred medications
- History of unacceptable or toxic side effects to preferred medications

Notes	*Note: PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
11/7/2019	C&S Implementation

Prior Authorization Guideline

GL-98984 Blood Formation, Coagulation, and Thrombosis Agents- Oral Anticoagulants

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: Savaysa	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Requested medication is being used for an approved FDA (Food and Drug Administration) indication and duration

AND **2** - One of the following **2.1** The patient cannot be changed to a preferred* medication due to ONE of the following acceptable reasons: • Allergy to preferred medications • Contraindication to all preferred medications • History of unacceptable/toxic side effects to preferred medications **OR** **2.2** Patient has failed a 14-day trial with TWO preferred* medications

Notes	*PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
11/30/2021	Removed Yosprala, Zontivity, Asprin/Omeprazole, Plavix and Effient to be placed in Blood Formation, Coagulation, and Thrombosis Agents – Oral Antiplatelet Guideline.

Prior Authorization Guideline

GL-98986 Blood Formation, Coagulation, and Thrombosis Agents- Oral Antiplatelet

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: Yosprala, aspirin-omeprazole, Zontivity, brand Plavix, brand Effient	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Requested medication is being used for an approved FDA (Food and Drug Administration) indication and duration

AND

2 - One of the following **2.1** The patient cannot be changed to a preferred* medication due to ONE of the following acceptable reasons: • Allergy to preferred medications • Contraindication to all preferred medications • History of unacceptable/toxic side effects to preferred medications **OR** **2.2** Patient has failed a 14 day trial with TWO preferred* medications	
Notes	*PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
11/30/2021	New guideline

Prior Authorization Guideline

GL-104585 Bosulif

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/1/2022

1 . Criteria

Product Name: Bosulif	
Diagnosis	Chronic Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient must have a diagnosis of chronic myeloid leukemia

AND

2 - One of the following:

2.1 Patient is not a candidate for imatinib as attested by physician

OR

2.2 Patient is currently on Bosulif therapy

Product Name: Bosulif	
Diagnosis	Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient must have a diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia

Product Name: Bosulif	
Diagnosis	Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient must have a diagnosis of myeloid/lymphoid neoplasms with eosinophilia

AND

2 - Presence of ABL1 (gene) rearrangement

Product Name: Bosulif	
Diagnosis	Chronic Myeloid Leukemia, Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia, Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Bosulif therapy

Product Name: Bosulif	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Bosulif will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Bosulif	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Bosulif therapy

2 . Revision History

Date	Notes
3/10/2022	GPI Updated

Prior Authorization Guideline

GL-109077 Braftovi

Formulary

Formulary Note

Guideline Note:

Effective Date:	9/1/2022

1 . Criteria

Product Name: Braftovi	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient must have ONE of the following diagnoses:

- Unresectable melanoma

- Metastatic melanoma

AND

2 - Patient is positive for BRAF V600 mutation

AND

3 - Braftovi will be used in combination with Mektovi (binimetinib)

AND

4 - ONE of the following:

4.1 Patient has a contraindication or history of intolerance to ONE of the following regimens:

- Tafinlar (dabrafenib) plus Mekinist (trametinib)
- Zelboraf (vemurafenib) plus Cotellic (cobimetinib)

OR

4.2 Provider attests that the patient is not an appropriate candidate for either of the following regimens:

- Tafinlar (dabrafenib) plus Mekinist (trametinib)
- Zelboraf (vemurafenib) plus Cotellic (cobimetinib)

OR

4.3 For continuation of prior Braftovi therapy

Product Name: Braftovi	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Braftovi therapy

AND

2 - Braftovi is used in combination with Mektovi (binimetinib)

Product Name: Braftovi	
Diagnosis	Colon Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient must have a diagnosis of colon cancer

AND

2 - Cancer is positive for BRAF V600E mutation

AND

3 - ONE of the following:

- Unresectable or advanced disease
- Metastatic disease

AND

4 - Patient has received prior therapy

AND

5 - Braftovi will be used in combination with ONE of the following:

- Erbitux (cetuximab)
- Vectibix (panitumumab)

Product Name: Braftovi	
Diagnosis	Colon Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Braftovi therapy

AND

2 - Used in combination with ONE of the following:

- Erbitux (cetuximab)
- Vectibix (panitumumab)

Product Name: Braftovi	
Diagnosis	Rectal Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient must have a diagnosis of rectal cancer

AND

2 - Cancer is positive for BRAF V600E mutation

AND

3 - ONE of the following:

- Unresectable or advanced disease
- Metastatic disease

AND

4 - Patient has received prior therapy

AND

5 - Braftovi will be used in combination with ONE of the following:

- Erbitux (cetuximab)
- Vectibix (panitumumab)

Product Name: Braftovi	
Diagnosis	Rectal Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Braftovi therapy

AND

2 - Used in combination with ONE of the following:

- Erbitux (cetuximab)
- Vectibix (panitumumab)

Product Name: Braftovi	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Braftovi	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Braftovi therapy

Prior Authorization Guideline

GL-99007 Brand Lyrica

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: Brand Lyrica IR capsules, Brand Lyrica solution	
Diagnosis	Seizures*
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient is new to plan and has been established on the medication within the previous 120 days	

OR

2 - The patient cannot be changed to a preferred medication due to ONE of the following reasons:

2.1 Allergy to TWO preferred medications

OR

2.2 Contraindication to or drug interaction with TWO preferred medications

OR

2.3 History of unacceptable/toxic side effects to TWO preferred medications

OR

3 - ONE of the following:

3.1 There has been a therapeutic failure to no less than TWO preferred products for a 30 day trial each**

OR

3.2 ALL of the following:

3.2.1 Prescription is submitted with the prescriber national provider identifier (NPI) of a physician who has registered a neurology specialty with Ohio Medicaid

AND

3.2.2 The request is for a standard tablet/capsule dosage form and is NOT a brand product with available generic alternatives

AND

3.2.3 Product is used only for seizures

AND

3.2.4 There has been a therapeutic failure to a trial of ONE preferred product for 30 days

Notes	*Applies to Central Nervous System (CNS) Agents: Anticonvulsants. PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Brand Lyrica IR capsules, Brand Lyrica solution	
Diagnosis	Fibromyalgia*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following:

1.1 Allergy to two preferred medications, in different classes below:

- Gabapentin
- Pregabalin
- Short- and/or long-acting opioids
- Skeletal muscle relaxants
- SNRIs (Serotonin and norepinephrine reuptake inhibitors)
- SSRIs (Selective serotonin reuptake inhibitors)
- Trazodone
- Tricyclic antidepressants

OR

1.2 Contraindication to all preferred medications

OR

1.3 History of unacceptable/toxic side effects to two preferred medications, in different classes below:

- Gabapentin
- Pregabalin
- Short- and/or long-acting opioids
- Skeletal muscle relaxants
- SNRIs
- SSRIs
- Trazodone
- Tricyclic antidepressants

OR

2 - Patient has trial of agents from two of the following drug classes for 14 days each in the past 90 days (guidelines suggest use of multiple agents concurrently to manage the signs of fibromyalgia):

- Gabapentin
- Pregabalin
- Short- and/or long-acting opioids
- Skeletal muscle relaxants
- SNRIs
- SSRIs
- Trazodone
- Tricyclic antidepressants

Notes	*Applies to Central Nervous System (CNS) Agents: Fibromyalgia Agents. PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html

Product Name: Brand Lyrica IR capsules, Brand Lyrica solution	
Diagnosis	Neuropathic Pain*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has had a therapeutic failure to no less than a 30-day trial of at least TWO preferred medications in separate pharmacologic classes **OR** **2** - ONE of the following: **2.1** Patient has allergy to preferred medications **OR** **2.2** Patient has a contraindication to or drug interaction with preferred medications **OR** **2.3** Patient has a history of unacceptable/toxic side effects to preferred medications	
Notes	*Applies to Central Nervous System (CNS) Agents: Neuropathic Pain. PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html

2 . Revision History

Date	Notes
11/30/2021	Removed step 2.4 in Anticonvulsant criteria

Prior Authorization Guideline

GL-84735 Bronchitol

Formulary

Formulary Note

Guideline Note:

Effective Date:	6/1/2021

1 . Criteria

Product Name: Bronchitol	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of cystic fibrosis (CF)	

AND

2 - Used in conjunction with standard CF therapies [e.g., chest physiotherapy, bronchodilators, antibiotics, anti-inflammatory therapy (e.g., ibuprofen, oral/inhaled corticosteroids)]

AND

3 - Patient has passed the Bronchitol Tolerance Test

Product Name: Bronchitol	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Bronchitol therapy

Prior Authorization Guideline

GL-96692 Brukinsa

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: Brukinsa	
Diagnosis	Mantle Cell Lymphoma (MCL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of mantle cell lymphoma (MCL)	

AND

2 - Patient has received at least one prior therapy for MCL

Product Name: Brukinsa	
Diagnosis	Marginal zone lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of marginal zone lymphoma

AND

2 - Disease is relapsed or refractory

AND

3 - Patient has received at least one anti-CD20-based regimen (e.g., rituximab, obinutuzumab)

Product Name: Brukinsa	
Diagnosis	MALT Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnosis

- Gastric mucosa-associated lymphoid tissue (MALT) lymphoma
- Non-Gastric mucosa-associated lymphoid tissue (MALT) lymphoma

AND

2 - Disease is recurrent, relapsed, refractory, or progressive

AND

3 - Used as second-line and subsequent therapy

AND

4 - Patient is intolerant to or has a contraindication to Imbruvica (ibrutinib)

Product Name: Brukinsa	
Diagnosis	Waldenström's Macroglobulinemia (WM)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Waldenström's macroglobulinemia (WM)

Product Name: Brukinsa	
Diagnosis	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL)

AND

2 - Contraindication to other bruton tyrosine kinase inhibitors (e.g., Imbruvica, Calquence)

Product Name: Brukinsa	
Diagnosis	Mantle Cell Lymphoma (MCL), Marginal zone lymphoma, MALT Lymphoma, Waldenström's Macroglobulinemia (WM), Chronic Lymphocytic Leukemia (CLL), Small Lymphocytic Lymphoma (SLL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Brukinsa therapy

Product Name: Brukinsa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Brukinsa will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Brukinsa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Brukinsa therapy	

2 . Revision History

Date	Notes
10/14/2021	Copy of NY

Prior Authorization Guideline

GL-62898 Buphenyl

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Brand Buphenyl oral powder, generic sodium phenylbutyrate oral powder	
Diagnosis	Urea Cycle Disorders (UCDs)
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of urea cycle disorders (UCDs)	

Product Name: Brand Buphenyl tablets, generic sodium phenylbutyrate tablets

Diagnosis	Urea Cycle Disorders (UCDs)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of urea cycle disorders (UCDs)

AND

2 - Prescriber provides a reason or special circumstance the patient cannot use Buphenyl (sodium phenylbutyrate) powder for oral solution

Product Name: Brand Buphenyl tablets, generic sodium phenylbutyrate tablets	
Diagnosis	Urea Cycle Disorders (UCDs)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Buphenyl (sodium phenylbutyrate) tablets

2 . Revision History

Date	Notes
3/6/2020	C&S Implementation

Prior Authorization Guideline

GL-101025 Bylvay

Formulary

Formulary Note

Guideline Note:

Effective Date:	3/1/2022

1 . Criteria

Product Name: Bylvay	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Confirmed molecular diagnosis of progressive familial intrahepatic cholestasis (PFIC) type 1 or 2

AND

2 - Patient does not have a ABCB11 variant resulting in non-functional or complete absence of bile salt export pump protein (BSEP-3)

AND

3 - Patient is experiencing moderate to severe pruritus associated with PFIC

AND

4 - Patient has a serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory

AND

5 - Patient has had an inadequate response to at least TWO other conventional treatments for the symptomatic relief of pruritus (e.g., bile acid-binding agents, naltrexone, phenobarbital, rifampin, ursodeoxycholic acid)

AND

6 - Prescribed by a hepatologist

Product Name: Bylvay	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Bylvay therapy (e.g., reduced serum bile acids, improved pruritis, and less sleep disturbance)

AND

2 - Prescribed by a hepatologist

Prior Authorization Guideline

GL-86348 Cablivi

Formulary

Formulary Note

Guideline Note:

Effective Date:	7/1/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Cablivi	
Diagnosis	Acquired thrombotic thrombocytopenic purpura (aTTP)
Approval Length	2 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP)

AND

2 - Cablivi was initiated as a bolus intravenous injection administered by a healthcare provider in combination with plasma exchange therapy

AND

3 - Cablivi will be used in combination with immunosuppressive therapy (e.g., corticosteroids)

AND

4 - Total treatment duration will be limited to 58 days beyond the last therapeutic plasma exchange

Product Name: Cablivi	
Diagnosis	Acquired thrombotic thrombocytopenic purpura (aTTP)
Approval Length	2 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Request is for a new (different) episode requiring the re-initiation of plasma exchange for the treatment of acquired thrombotic thrombocytopenic purpura (aTTP) (Documentation of date of prior episode and documentation date of new episode required)

2 . Revision History

Date	Notes
5/3/2021	Copy of NY

Prior Authorization Guideline

GL-99357 Cabometyx

Formulary

Formulary Note

Guideline Note:

Effective Date:	2/1/2022

1 . Criteria

Product Name: Cabometyx	
Diagnosis	Renal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced renal cell carcinoma

Product Name: Cabometyx	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Positive for RET gene rearrangements

Product Name: Cabometyx	
Diagnosis	Hepatocellular Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hepatocellular carcinoma

AND

2 - ONE of the following:

2.1 History of failure or intolerance to Nexavar (sorafenib)

OR

2.2 Patient has metastatic disease

OR

2.3 Patient has extensive liver tumor burden

OR

2.4 Patient is inoperable by performance status or comorbidity, or has local disease or local disease with minimal extrahepatic disease only

OR

2.5 BOTH of the following:

- Patient is not a transplant candidate
- Disease is unresectable

Product Name: Cabometyx	
Diagnosis	Osteosarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of osteosarcoma

AND

2 - Patient's disease has progressed on prior treatment

AND

3 - ONE of the following:

3.1 Patient has relapsed/refractory disease

OR

3.2 Patient has metastatic disease

Product Name: Cabometyx	
Diagnosis	Ewing Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Ewing sarcoma (including mesenchymal chondrosarcoma)

AND

2 - Patient has relapsed, progressive, or metastatic disease

Product Name: Cabometyx	
Diagnosis	Gastrointestinal Stromal Tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumors (GIST)

AND

2 - Patient has unresectable, recurrent, or metastatic disease after failure on approved therapies (e.g., imatinib)

Product Name: Cabometyx	
Diagnosis	Kidney Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of kidney cancer

AND

2 - ONE of the following:

2.1 Patient has relapsed disease

OR

2.2 Patient has metastatic disease

Product Name: Cabometyx	
Diagnosis	Endometrial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of endometrial carcinoma

AND

2 - Disease is recurrent, high-risk, or metastatic

AND

3 - Used as second-line treatment

Product Name: Cabometyx	
Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of differentiated thyroid cancer (DTC)

AND

2 - Disease is locally advanced or metastatic

AND

3 - Disease has progressed following prior VEGFR-targeted therapy

AND

4 - Disease is radioactive iodine-refractory or ineligible

Product Name: Cabometyx	
Diagnosis	Renal Cell Carcinoma, Non-small cell lung cancer (NSCLC), Hepatocellular Carcinoma, Osteosarcoma, Ewing Sarcoma, Gastrointestinal Stromal Tumors, Kidney Cancer, Endometrial Carcinoma, Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Cabometyx therapy

Product Name: Cabometyx	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Cabometyx will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Cabometyx	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cabometyx therapy

2 . Revision History

Date	Notes
12/7/2021	Updated GPI's and criteria to include Endometrial carcinoma and ne w indication for thyroid cancer

Prior Authorization Guideline

GL-108103 Calquence

Formulary

Formulary Note

Guideline Note:

Effective Date:	8/1/2022

1 . Criteria

Product Name: Calquence	
Diagnosis	Mantle cell lymphoma (MCL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of mantle cell lymphoma (MCL)	

AND

2 - Patient has received at least one prior therapy for MCL [e.g., Rituxan (rituximab)]

Product Name: Calquence	
Diagnosis	Chronic lymphocytic leukemia/small lymphocytic lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia/small lymphocytic lymphoma

Product Name: Calquence	
Diagnosis	B-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Nodal Marginal Zone Lymphoma
- Gastric Mucosa-Associated Lymphoid Tissue (MALT) Lymphoma
- Splenic Marginal Zone Lymphoma
- Non-gastric MALT Lymphoma (non-cutaneous)

AND

2 - Disease is recurrent, relapsed, refractory, or progressive

AND

3 - Patient has an intolerance or contraindication to Imbruvica (ibrutinib) (please specify intolerance or contraindication)

Product Name: Calquence	
Diagnosis	Waldenström Macroglobulinemia/ Lymphoplasmacytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Waldenström Macroglobulinemia/ Lymphoplasmacytic Lymphoma

AND

2 - ONE of the following:

- Patient did not respond to primary therapy
- Disease is relapsed or progressive

Product Name: Calquence	
Diagnosis	Mantle cell lymphoma (MCL), Chronic lymphocytic leukemia/small lymphocytic lymphoma, B-Cell Lymphomas, Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Calquence therapy

Product Name: Calquence	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Calquence	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Calquence therapy

2 . Revision History

Date	Notes
6/13/2022	Added clarification on contraindication or intolerance to Imbruvica for B-cell Lymphomas.

Prior Authorization Guideline

GL-96860 Caprelsa

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: Caprelsa	
Diagnosis	Medullary thyroid cancer (MTC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of medullary thyroid cancer (MTC)	

AND

2 - ONE of the following:

- Unresectable locally advanced disease
- Metastatic disease

AND

3 - ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

Product Name: Caprelsa	
Diagnosis	Medullary thyroid cancer (MTC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Caprelsa therapy

Product Name: Caprelsa	
Diagnosis	Follicular carcinoma, Hürthle cell carcinoma, Papillary carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Follicular carcinoma
- Hürthle cell carcinoma
- Papillary carcinoma

AND

2 - One of the following:

- Unresectable recurrent disease
- Persistent locoregional disease
- Metastatic disease

AND

3 - One of the following:

- Patient has symptomatic disease
- Patient has progressive disease

AND

4 - Disease is refractory to radioactive iodine treatment

Product Name: Caprelsa	
Diagnosis	Follicular carcinoma, Hürthle cell carcinoma, Papillary carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Caprelsa therapy

Product Name: Caprelsa	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Non-Small Cell Lung Cancer (NSCLC)

AND

2 - Disease is positive for RET gene rearrangement

Product Name: Caprelsa	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Caprelsa therapy

Product Name: Caprelsa	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Caprelsa	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Caprelsa therapy	

2 . Revision History

Date	Notes
10/18/2021	Update

Prior Authorization Guideline

GL-89951 Carbaglu

Formulary

Formulary Note

Guideline Note:

Effective Date:	10/1/2021

1 . Criteria

Product Name: Carbaglu	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hyperammonemia due to ONE of the following:

- N-acetylglutamate synthase (NAGS) deficiency
- Propionic acidemia (PA)

- Methylmalonic acidemia (MMA)

Product Name: Carbaglu	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Carbaglu therapy

Prior Authorization Guideline

GL-107463 Cardiovascular Agents - Lipotropics

Formulary

Formulary Note

Guideline Note:

Effective Date:	7/1/2022

1 . Criteria

Product Name: Altoprev, Brand Caduet, generic amlodipine/atorvastatin, Brand Colestid, generic colestipol granules/packet, Brand Vytorin, generic ezetimibe/simvastatin, Ezallor Sprinkle, fluvastatin, Livalo, Brand Niaspan, generic niacin ER tabs (Rx only), Brand Vascepa, generic icosapent, Zypitamag, Brand Lipitor, Brand Questran, Brand Questran Light, Brand Zetia, Brand Lovaza, Brand Crestor, Brand Zocor, Brand Lescol XL ,generic fluvastatin ER	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient cannot be changed to a preferred* medication due to ONE of the following:	

- Allergy to preferred medications
- Contraindication to or drug-to-drug interaction with preferred medications [pravastatin is the ONLY HMG-CoA (3-hydroxy-3-methylglutaryl coenzyme A) not metabolized by the cytochrome P450 liver enzyme system]
- History of unacceptable/toxic side effects to preferred medications

OR

2 - ONE of the following:

2.1 If the request is for an HMG-CoA (statin) medication, patient has had a 30-day trial with no less than TWO preferred* HMG-CoA products

OR

2.2 Patient has had a 30-day trial with 1 preferred* medication in the same class, if available

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Lipofen, fenofibrate caps, Brand Fenoglide, generic fenofibrate 40mg and 120mg tabs, Brand Tricor tabs, generic fenofibrate 54 mg and 160 mg tabs, Brand Antara, generic fenofibrate micronized 30mg, 43mg, 90mg and 130mg caps, fenofibric micronized 67mg, 134 mg ad 200mg caps (generic for Tricor micronized caps), Brand Trilipix, generic fenofibric acid DR cap, Fibricor, fenofibric acid tab, Brand Lopid	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient cannot be changed to a preferred* medication due to ONE of the following:

- Allergy to preferred medications
- Contraindication to or drug-to-drug interaction with preferred medications [pravastatin is the ONLY HMG-CoA (3-hydroxy-3-methylglutaryl coenzyme A) not metabolized by the cytochrome P450 liver enzyme system]
- History of unacceptable/toxic side effects to preferred medications

OR

2 - Patient has had a 90-day trial with 1 preferred* medication in the same class	
Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Brand Welchol, generic colesevelam	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient cannot be changed to a preferred* medication due to ONE of the following:

- Allergy to preferred medications
- Contraindication to or drug-to-drug interaction with preferred medications [pravastatin is the ONLY HMG-CoA (3-hydroxy-3-methylglutaryl coenzyme A) not metabolized by the cytochrome P450 liver enzyme system]
- History of unacceptable/toxic side effects to preferred medications

OR

2 - Patient has had a 30-day trial with 1 preferred* medication in the same class

OR

3 - Request is for first-line therapy and patient has a diagnosis of diabetes

OR

4 - Patient has a history of an oral hypoglycemic or insulin in the previous 120 days

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Praluent, Repatha Sureclick, Repatha Pushtronex, Repatha	
Diagnosis	Heterozygous Familial Hypercholesterolemia (HeFH), Homozygous Familial Hypercholesterolemia (HoFH)

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

1.1 Heterozygous Familial Hypercholesterolemia (HeFH)

OR

1.2 Homozygous Familial Hypercholesterolemia (HoFH)

AND

2 - ONE of the following:

2.1 If the request is for Repatha, the patient is greater than or equal to 10 years of age

OR

2.2 If the request is for Praluent, the patient is greater than or equal to 18 years of age

AND

3 - Documentation of baseline lipid profile

AND

4 - Documented adherence to prescribed lipid lowering medications for previous 90 days

AND

5 - Trial of TWO high potency statins (e.g.; atorvastatin, rosuvastatin)

AND

6 - ONE of the following:

6.1 If the patient is less than 18 years of age, they are unable to reach the LDL-C (low-density lipoprotein cholesterol) goal of less than or equal to 110 milligrams per deciliter with maximally tolerated dose of statin and ezetimibe (Zetia)

OR

6.2 If the patient is greater than or equal to 18 years of age, they are unable to reach the LDL-C (low-density lipoprotein cholesterol) goal of less than or equal to 100 milligrams per deciliter with maximally tolerated dose of statin and ezetimibe (Zetia)

Product Name: Praluent, Repatha Sureclick, Repatha Pushtronex, Repatha	
Diagnosis	Atherosclerotic Cardiovascular Disease (ASCVD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Atherosclerotic Cardiovascular Disease (ASCVD)

AND

2 - The patient is greater than or equal to 18 years of age

AND

3 - Patient has a history of MI (myocardial infarction), angina, coronary or other arterial revascularization, stroke, transient ischemic attack (TIA), or peripheral vascular disease (PVD) of atherosclerotic origin

AND

4 - Documentation of baseline lipid profile

AND

5 - Documented adherence to prescribed lipid lowering medications for previous 90 days

AND

6 - Trial of TWO high potency statins (e.g.; atorvastatin, rosuvastatin)

AND

7 - Patient is unable to reach goal LDL-C (low-density lipoprotein cholesterol) of less than 70 milligrams per deciliter with maximally tolerated dose of statin and ezetimibe (Zetia)

Product Name: Praluent, Repatha Sureclick, Repatha Pushtronex, Repatha	
Diagnosis	Heterozygous Familial Hypercholesterolemia (HeFH), Homozygous Familial Hypercholesterolemia (HoFH), Atherosclerotic Cardiovascular Disease (ASCVD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of improvement in lipid levels while on requested therapy

OR

2 - Attestation of clinical stabilization

Product Name: Juxtapid	
Diagnosis	Homozygous Familial Hypercholesterolemia (HoFH)
Approval Length	180 Day(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is greater than or equal to 18 years of age

AND

2 - Diagnosis of Homozygous Familial Hypercholesterolemia (HoFH)

AND

3 - Documentation of baseline lipid profile

AND

4 - One of the following:

4.1 Patient is unable to reach goal LDL-C (low-density lipoprotein cholesterol) of less than 100 milligrams per deciliter with high-potency statin therapy (atorvastatin or rosuvastatin), ezetimibe and PCSK9 (proprotein convertase subtilisin/kexin type 9) inhibitor

OR

4.2 Clinical reason high-potency statin therapy (atorvastatin or rosuvastatin), ezetimibe and PCSK9 inhibitor cannot be utilized

Product Name: Juxtapid	
Diagnosis	Homozygous Familial Hypercholesterolemia (HoFH)
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of improvement in lipid levels while on requested therapy

OR

2 - Attestation of clinical stabilization

Product Name: Nexletol, Nexlizet	
Approval Length	84 Day(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 18 years of age or older

AND

2 - Patient had a trial and failure with one PCSK9 (proprotein convertase subtilisin/kexin type 9) inhibitor

AND

3 - BOTH of the following:

3.1 Patient is unable to reach goal low density lipoprotein cholesterol (LDL-C) after a trial of 2 or more statins (one must be atorvastatin) at the maximally tolerated dose

AND

3.2 If the request is for Nexlizet, one of the previous statin trials must be in combination with ezetimibe (Zetia)

AND

4 - Documented adherence to prescribed lipid lowering medications for previous 90 days

AND

5 - Documentation of baseline lipid profile

Product Name: Nexletol, Nexlizet	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of improvement in lipid levels while on requested therapy

OR

2 - Attestation of clinical stabilization

2 . Revision History

Date	Notes
5/24/2022	Added SP formulary

Prior Authorization Guideline

GL-107463 Cardiovascular Agents - Lipotropics

Formulary

Formulary Note

Guideline Note:

Effective Date:	7/1/2022

1 . Criteria

Product Name: Altoprev, Brand Caduet, generic amlodipine/atorvastatin, Brand Colestid, generic colestipol granules/packet, Brand Vytorin, generic ezetimibe/simvastatin, Ezallor Sprinkle, fluvastatin, Livalo, Brand Niaspan, generic niacin ER tabs (Rx only), Brand Vascepa, generic icosapent, Zypitamag, Brand Lipitor, Brand Questran, Brand Questran Light, Brand Zetia, Brand Lovaza, Brand Crestor, Brand Zocor, Brand Lescol XL ,generic fluvastatin ER	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient cannot be changed to a preferred* medication due to ONE of the following:

- Allergy to preferred medications

- Contraindication to or drug-to-drug interaction with preferred medications [pravastatin is the ONLY HMG-CoA (3-hydroxy-3-methylglutaryl coenzyme A) not metabolized by the cytochrome P450 liver enzyme system]
- History of unacceptable/toxic side effects to preferred medications

OR

2 - ONE of the following:

2.1 If the request is for an HMG-CoA (statin) medication, patient has had a 30-day trial with no less than TWO preferred* HMG-CoA products

OR

2.2 Patient has had a 30-day trial with 1 preferred* medication in the same class, if available

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Lipofen, fenofibrate caps, Brand Fenoglide, generic fenofibrate 40mg and 120mg tabs, Brand Tricor tabs, generic fenofibrate 54 mg and 160 mg tabs, Brand Antara, generic fenofibrate micronized 30mg, 43mg, 90mg and 130mg caps, fenofibric micronized 67mg, 134 mg ad 200mg caps (generic for Tricor micronized caps), Brand Trilipix, generic fenofibric acid DR cap, Fibricor, fenofibric acid tab, Brand Lopid

Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient cannot be changed to a preferred* medication due to ONE of the following:

- Allergy to preferred medications
- Contraindication to or drug-to-drug interaction with preferred medications [pravastatin is the ONLY HMG-CoA (3-hydroxy-3-methylglutaryl coenzyme A) not metabolized by the cytochrome P450 liver enzyme system]
- History of unacceptable/toxic side effects to preferred medications

OR

2 - Patient has had a 90-day trial with 1 preferred* medication in the same class

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Brand Welchol, generic colesevelam	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient cannot be changed to a preferred* medication due to ONE of the following:

- Allergy to preferred medications
- Contraindication to or drug-to-drug interaction with preferred medications [pravastatin is the ONLY HMG-CoA (3-hydroxy-3-methylglutaryl coenzyme A) not metabolized by the cytochrome P450 liver enzyme system]
- History of unacceptable/toxic side effects to preferred medications

OR

2 - Patient has had a 30-day trial with 1 preferred* medication in the same class

OR

3 - Request is for first-line therapy and patient has a diagnosis of diabetes

OR

4 - Patient has a history of an oral hypoglycemic or insulin in the previous 120 days

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Praluent, Repatha Sureclick, Repatha Pushtronex, Repatha	
Diagnosis	Heterozygous Familial Hypercholesterolemia (HeFH), Homozygous Familial Hypercholesterolemia (HoFH)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

1.1 Heterozygous Familial Hypercholesterolemia (HeFH)

OR

1.2 Homozygous Familial Hypercholesterolemia (HoFH)

AND

2 - ONE of the following:

2.1 If the request is for Repatha, the patient is greater than or equal to 10 years of age

OR

2.2 If the request is for Praluent, the patient is greater than or equal to 18 years of age

AND

3 - Documentation of baseline lipid profile

AND

4 - Documented adherence to prescribed lipid lowering medications for previous 90 days

AND

5 - Trial of TWO high potency statins (e.g.; atorvastatin, rosuvastatin)

AND

6 - ONE of the following:

6.1 If the patient is less than 18 years of age, they are unable to reach the LDL-C (low-density lipoprotein cholesterol) goal of less than or equal to 110 milligrams per deciliter with maximally tolerated dose of statin and ezetimibe (Zetia)

OR

6.2 If the patient is greater than or equal to 18 years of age, they are unable to reach the LDL-C (low-density lipoprotein cholesterol) goal of less than or equal to 100 milligrams per deciliter with maximally tolerated dose of statin and ezetimibe (Zetia)

Product Name: Praluent, Repatha Sureclick, Repatha Pushtronex, Repatha	
Diagnosis	Atherosclerotic Cardiovascular Disease (ASCVD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Atherosclerotic Cardiovascular Disease (ASCVD)

AND

2 - The patient is greater than or equal to 18 years of age

AND

3 - Patient has a history of MI (myocardial infarction), angina, coronary or other arterial revascularization, stroke, transient ischemic attack (TIA), or peripheral vascular disease (PVD) of atherosclerotic origin

AND

4 - Documentation of baseline lipid profile

AND

5 - Documented adherence to prescribed lipid lowering medications for previous 90 days

AND

6 - Trial of TWO high potency statins (e.g.; atorvastatin, rosuvastatin)

AND

7 - Patient is unable to reach goal LDL-C (low-density lipoprotein cholesterol) of less than 70 milligrams per deciliter with maximally tolerated dose of statin and ezetimibe (Zetia)

Product Name: Praluent, Repatha Sureclick, Repatha Pushtronex, Repatha	
Diagnosis	Heterozygous Familial Hypercholesterolemia (HeFH), Homozygous Familial Hypercholesterolemia (HoFH), Atherosclerotic Cardiovascular Disease (ASCVD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of improvement in lipid levels while on requested therapy

OR

2 - Attestation of clinical stabilization

Product Name: Juxtapid	
Diagnosis	Homozygous Familial Hypercholesterolemia (HoFH)
Approval Length	180 Day(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is greater than or equal to 18 years of age

AND

2 - Diagnosis of Homozygous Familial Hypercholesterolemia (HoFH)

AND

3 - Documentation of baseline lipid profile

AND

4 - One of the following:

4.1 Patient is unable to reach goal LDL-C (low-density lipoprotein cholesterol) of less than 100 milligrams per deciliter with high-potency statin therapy (atorvastatin or rosuvastatin), ezetimibe and PCSK9 (proprotein convertase subtilisin/kexin type 9) inhibitor

OR

4.2 Clinical reason high-potency statin therapy (atorvastatin or rosuvastatin), ezetimibe and PCSK9 inhibitor cannot be utilized

Product Name: Juxtapid	
Diagnosis	Homozygous Familial Hypercholesterolemia (HoFH)
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of improvement in lipid levels while on requested therapy

OR

2 - Attestation of clinical stabilization

Product Name: Nexletol, Nexlizet	
Approval Length	84 Day(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 18 years of age or older

AND

2 - Patient had a trial and failure with one PCSK9 (proprotein convertase subtilisin/kexin type 9) inhibitor

AND

3 - BOTH of the following:

3.1 Patient is unable to reach goal low density lipoprotein cholesterol (LDL-C) after a trial of 2 or more statins (one must be atorvastatin) at the maximally tolerated dose

AND

3.2 If the request is for Nexlizet, one of the previous statin trials must be in combination with ezetimibe (Zetia)

AND

4 - Documented adherence to prescribed lipid lowering medications for previous 90 days

AND

5 - Documentation of baseline lipid profile

Product Name: Nexletol, Nexlizet	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of improvement in lipid levels while on requested therapy

OR

2 - Attestation of clinical stabilization

2 . Revision History

Date	Notes
5/24/2022	Added SP formulary

Prior Authorization Guideline

GL-78690 Cardiovascular Agents - Pulmonary Arterial Hypertension

Formulary

Formulary Note

Guideline Note:

Effective Date:	2/1/2021

1 . Criteria

Product Name: Brand and generic Adcirca, Alyq, Brand and generic Tracleer tablets and oral susp, Brand and generic Letairis, Opsumit, Orenitram, Uptravi, Brand and generic Revatio tablets and oral susp	
Diagnosis	Pulmonary Arterial Hypertension (PAH)
Approval Length	365 Day(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has a diagnosis of Pulmonary Arterial Hypertension (PAH)	

AND

2 - If the requested medication is non-preferred*, ONE of the following:

2.1 Patient is new to plan and has taken the requested medication within the previous 120 days

OR

2.2 Patient has failed a therapeutic trial of 30 days with two preferred medications, one of which is a preferred Phosphodiesterase-5 Inhibitor

OR

2.3 Patient has an allergy to preferred medications

OR

2.4 Patient has a contraindication to all preferred medications

OR

2.5 Patient has a history of unacceptable/toxic side effects to preferred medications

OR

2.6 If the request is for an inhalation or intravenous formulation, the patient has class 3 or 4 symptoms defined by the NYHA (New York Heart Association) Functional Class for Pulmonary Hypertension

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Adempas

Diagnosis	Chronic Thromboembolic Pulmonary Hypertension (CTEPH), Pulmonary Arterial Hypertension (PAH)
Approval Length	365 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Patient has a diagnosis of persistent/recurrent Chronic Thromboembolic Pulmonary Hypertension (CTEPH) classified as WHO Group 4

AND

1.2 ONE of the following:

- Has had surgical treatment
- Has inoperable CTEPH

OR

2 - BOTH of the following:

2.1 Patient has a diagnosis of Pulmonary Arterial Hypertension (PAH)

AND

2.2 If the requested medication is non-preferred*, ONE of the following:

2.2.1 Patient is new to plan and has taken the requested medication within the previous 120 days

OR

2.2.2 Patient has failed a therapeutic trial of 30 days with two preferred medications, one of which is a preferred Phosphodiesterase-5 Inhibitor

OR

2.2.3 Patient has an allergy to preferred medications

OR

2.2.4 Patient has a contraindication to all preferred medications

OR

2.2.5 Patient has a history of unacceptable/toxic side effects to preferred medications

OR

2.2.6 If the request is for an inhalation or intravenous formulation, the patient has class 3 or 4 symptoms defined by the NYHA (New York Heart Association) Functional Class for Pulmonary Hypertension

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
12/21/2020	Updated criteria

Prior Authorization Guideline

GL-103815 Cardiovascular Agents- Angina, Hypertension and Heart Failure

Formulary

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Brand Corlanor	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of stable, symptomatic heart failure

AND

2 - Left ventricular ejection fraction less than or equal to 35%

AND

3 - Resting heart rate is greater than or equal to 70 beats per minute (bpm)

AND

4 - The patient is in sinus rhythm

AND

5 - One of the following:

5.1 The patient has persisting heart failure symptoms with maximally tolerated doses of beta blockers

OR

5.2 The patient has a contraindication to beta blocker therapy

Product Name: Brand Entresto	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic heart failure New York Heart Association (NYHA) Class II-IV

AND

2 - Patient has reduced left ventricular ejection fraction

Product Name: Brand Tekturna, generic aliskiren, brand Tekturna HCT	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - History of a 30 day trial of any ONE preferred* anti-hypertensive agent	
Notes	*OH PDL: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Qbrelis, Prestalia, Carospir, Edarbi, Edarbyclor, Kapspargo Sprinkle, Sotylize, isradipine, nimodipine, brand Sular, generic nisoldipine ER, Katerzia, brand Norvasc, brand Atacand, generic candesartan, brand Atacand HCT, generic candesartan/HCTZ, brand Exforge, brand Exforge HCT, brand Lotrel, brand Azor, brand Tenormin, brand Tenoretic, brand Lotensin, brand Lotensin HCT, brand Ziac, brand Coreg, brand Coreg CR, generic carvedilol ER caps, brand Cardizem, brand Cardizem CD, brand Cardizem LA, Matzim LA, Cardura, Vasotec, Vaseretic, brand Inspra, brand Innopran XL, brand Inderal XL, brand Avapro, brand Avalide, brand Zestril, brand Zestoretic, Brand Cozaar, brand Hyzaar, brand Toprol XL, brand Lopressor, brand Corgard, brand Procardia XL, brand Minipress, brand Accupril, brand Accuretic, brand Altace, brand Ranexa, brand Betapace, brand Aldactone, brand Aldactazide, brand Tiazac, brand Mavik, brand Diovan, brand Diovan HCT, brand Verelan, brand Verelan PM, generic verapamil 200, 300mg ER cap, brand Nymalize, brand Benicar, brand Benicar HCT, brand Tribenzor, brand Micardis, generic telmisartan, brand Micardis HCT, generic telmisartan/HCTZ, brand Calan SR, diltiazem 24H ER tab, Nebivolol, Enalapril solution, Catapres TTS patch	
Approval Length	Nimodipine after a subarachnoid hemorrhage is 21 days; all others are 12 months.
Guideline Type	Prior Authorization
Approval Criteria **1** - The patient cannot be changed to a preferred* medication due to ONE of the following acceptable reasons **1.1** Allergy to all preferred medications **OR** **1.2** Contraindication to or drug-to-drug interaction with preferred medications	

OR

1.3 History of unacceptable/toxic side effects to preferred medications

OR

2 - BOTH of the following

2.1 Therapeutic failure to no less than a 30-day trial of TWO preferred* medications within the same class

AND

2.2 The requested medication's corresponding generic (if covered by the state) has been attempted and failed or is contraindicated

OR

3 - There is a specific indication for a medication requiring prior approval, for which preferred medications are not indicated, then may approve the requested medication. This medication should be reviewed for need at each request for reauthorization

Notes	*OH PDL: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Verquvo	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of symptomatic chronic heart failure New York Heart Association (NYHA) Class II-IV

AND

2 - Left ventricular ejection fraction less than 45%

AND

3 - ONE of the following

3.1 Patient has been hospitalized for the treatment of heart failure within the previous 180 day

OR

3.2 Patient needs treatment with an outpatient intravenous diuretic within the previous 90 days

AND

4 - Patient must be treated with an agent from ALL of the following medication classes (unless contradicted)

- Angiotensin-converting enzyme inhibitor, angiotensin II receptor blocker, or an angiotensin receptor neprilysin inhibitor
- Beta-blocker
- Aldosterone antagonist and/or SGLT2 inhibitor as appropriate for renal function

Notes	*OH PDL: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Kerendia	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Chronic Kidney Disease due to Type 2 Diabetes

AND

2 - The patient is on a maximum tolerated dose of an angiotensin-converting enzyme inhibitor or angiotensin receptor blocker

AND

3 - The patient has allergy, intolerance, or inadequate response to an SGLT2 inhibitor

2 . Revision History

Date	Notes
2/17/2022	Added Kerendia and state mandated criteria

Prior Authorization Guideline

GL-56862 Cardiovascular Agents- Antiarrhythmics

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2020

1 . Criteria

Product Name: Amiodarone 100mg, Amiodarone 400mg, Multaq	
Approval Length	365 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has one of the following:

1.1 Allergy to medications not requiring prior approval*

OR **1.2** Contraindication to all medications not requiring prior approval* **OR** **1.3** History of unacceptable/toxic side effects to medications not requiring prior approval* **OR** **2** - The patient has failed a therapeutic trial of 30 days with one medication not requiring prior approval*

Notes	*OH PDL: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
11/13/2019	New Program

Prior Authorization Guideline

GL-107395 Central Nervous System (CNS) Agents - Anticonvulsants

Formulary

Formulary Note

Guideline Note:

Effective Date:	7/1/2022

1 . Criteria

Product Name: Oxtellar XR, Celontin, generic Clonazepam ODT, brand Onfi, Sympazan, Briviact, brand Felbatol, generic Felbamate, generic Lamotrigine kits, brand Lamictal ODT, generic Lamotrigine ODT, brand Lamictal XR, generic Lamotrigine ER, brand Keppra XR, generic Levetiracetam ER Tablet, brand Qudexy XR, generic Topiramte ER, brand Sabril Tablet, generic Vigabatrin Tablet, Spritam, Subvenite, brand Gabitril, generic tiagabine, generic topiramate sprinkle cap, Trokendi XR, Aptiom, brand Klonopin, brand Depakote, brand Depakote ER, brand Zarontin, brand Dilantin, brand Phenytek, brand Mysoline, brand Lamictal, brand Keppra, brand Topamax, brand Zonegran, generic rufinamide, Fintepla, Xcopri, Elepsia XR, generic lacosamide	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is new to plan and has been established on the medication within the previous 120 days

OR

2 - The patient cannot be changed to a preferred medication due to ONE of the following reasons:

2.1 Allergy to TWO preferred medications*

OR

2.2 Contraindication to or drug interaction with TWO preferred medications*

OR

2.3 History of unacceptable/toxic side effects to TWO preferred medications*

OR

3 - ONE of the following:

3.1 There has been a therapeutic failure to no less than TWO preferred products for a 30 day trial each*

OR

3.2 ALL of the following:

3.2.1 Prescription is submitted with the prescriber national provider identifier (NPI) of a physician who has registered a neurology specialty with Ohio Medicaid

AND

3.2.2 The request is for a standard tablet/capsule dosage form and is NOT a brand product with available generic alternatives

AND

3.2.3 Product is used only for seizures

AND

3.2.4 There has been a therapeutic failure to a trial of ONE preferred product for 30 days*

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Epidiolex*	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

1.1.1 The patient has ONE of the following diagnoses:

- Lennox-Gastaut syndrome
- Tuberous sclerosis complex

AND

1.1.2 The patient has trialed and failed (inadequate seizure control or intolerance) THREE prior anticonvulsant therapies for 30 days each

OR

1.2 The patient has a diagnosis of Dravet syndrome

AND

2 - The prescriber has obtained serum transaminases (alanine aminotransferase [ALT] and aspartate aminotransferase [AST]) and total bilirubin levels prior to starting therapy

AND

3 - The prescriber must submit documented average number of seizure days per month (measured monthly or quarterly)

AND

4 - ONE of the following:

- For Lennox-Gastaut syndrome or Dravet syndrome: The maximum daily dose (quantity limit) does not exceed 20 milligrams per kilogram per day (titration based on response/tolerability)
- For tuberous sclerosis complex: The maximum daily dose does not exceed 25 milligrams per kilogram per day (titration based on response/tolerability)

Notes	*Excluded from Grandfathering

Product Name: Epidiolex*	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documented reduction in average number of seizure days per month (measured monthly or quarterly)

Notes	*Excluded from Grandfathering

Product Name: Diacomit*	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of Dravet Syndrome

AND

2 - Medication is prescribed by a neurologist or in consultation with a neurologist

AND

3 - Patient has baseline hematologic testing (complete blood count [CBC]) (Prescribers must include management plans for patients with neutrophil counts less than 1500 cells per cubic millimeter [cells/mm3] or platelet count less than 150,000 per microliter)

AND

4 - The prescriber has addressed any co-morbid conditions (Patients with phenylketonuria (PKU) will not be authorized for suspension dosage form without evidence of total daily amount of phenylalanine)

AND

5 - Patient must be concurrently managed with clobazam

AND

6 - Dose will be restricted based upon patient weight to 50 milligrams per kilogram per day AND the requested dose does not exceed 3000 milligrams per day

AND **7** - Prescriber must submit documented average number of seizure days per month (measured monthly or quarterly)
Notes | *Excluded from Grandfathering

Product Name: Diacomit*	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documented reduction in average number of seizure days per month (measured monthly or quarterly)	
Notes	*Excluded from Grandfathering

Product Name: Fycompa, Brand Vimpat	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria **1** - Inadequate clinical response to a 30 day trial of one preferred anticonvulsant	

Product Name: Brand Sabril Powder, generic Vigabatrin Powder, Vigadrone	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - The patient is less than or equal to 2 years of age	

OR

2 - The patient is greater than 2 years of age and ONE of the following:

2.1 Patient is new to plan and has been established on the medication within the previous 120 days

OR

2.2 The patient cannot be changed to a preferred medication due to ONE of the following reasons:

2.2.1 Allergy to TWO preferred medications*

OR

2.2.2 Contraindication to or drug interaction with TWO preferred medications*

OR

2.2.3 History of unacceptable/toxic side effects to TWO preferred medications*

OR

2.3 ONE of the following:

2.3.1 There has been a therapeutic failure to no less than TWO preferred products for a 30 day trial each*

OR

2.3.2 ALL of the following:

2.3.2.1 Prescription is submitted with the prescriber national provider identifier (NPI) of a physician who has registered a neurology specialty with Ohio Medicaid

AND

2.3.2.2 The request is for a standard tablet/capsule dosage form and is NOT a brand product with available generic alternatives

AND

2.3.2.3 Product is used only for seizures

AND

2.3.2.4 There has been a therapeutic failure to a trial of ONE preferred product for 30 days*

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Eprontia	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient is less than 12 years of age

OR

2 - The patient is 12 years of age or older and ONE of the following:

2.1 Patient is new to plan and has been established on the medication within the previous 120 days

OR

2.2 The patient cannot be changed to a preferred medication due to ONE of the following reasons:

2.2.1 Allergy to TWO preferred medications*

OR

2.2.2 Contraindication to or drug interaction with TWO preferred medications*

OR

2.2.3 History of unacceptable/toxic side effects to TWO preferred medications*

OR

2.3 ONE of the following:

2.3.1 There has been a therapeutic failure to no less than TWO preferred products for a 30 day trial each*

OR

2.3.2 ALL of the following:

2.3.2.1 Prescription is submitted with the prescriber national provider identifier (NPI) of a physician who has registered a neurology specialty with Ohio Medicaid

AND

2.3.2.2 The request is for a standard tablet/capsule dosage form and is NOT a brand product with available generic alternatives

AND

2.3.2.3 Product is used only for seizures

AND **2.3.2.4** There has been a therapeutic failure to a trial of ONE preferred product for 30 days*
Notes | *PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
5/24/2022	Updated GPI's and Vigabatrin powder criteria. Added Eprontia and criteria.

Prior Authorization Guideline

GL-109485 Central Nervous System (CNS) Agents - Anti-Migraine Agents

Formulary

Formulary Note

Guideline Note:

Effective Date:	7/24/2022

1 . Criteria

Product Name: Nurtec ODT	
Diagnosis	Acute Migraine Treatment
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient has had an inadequate clinical response to a 14-day trial of TWO preferred medications*

OR

1.2 Patient has ONE of the following:

- Allergy to preferred* medications
- Contraindication to all preferred* medications
- History of unacceptable/toxic side effects to at least two preferred* medications

Notes	*OH PDL: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: almotriptan, Onzetra Xsail, brand Relpax, generic eletriptan, brand Zomig tablets, generic zolmitriptan tablets, zolmitriptan orally disintegrating tablets, brand Zomig Nasal Spray, generic zolmitriptan Nasal Spray, brand Frova, generic frovatriptan, brand Treximet, generic sumatriptan/naproxen, Tosymra, Ergomar, Migergot, Brand Migranal, generic dihydroergotamine nasal spray, Reyvow, Ubrelvy, Trudhesa	
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 The patient has had an inadequate clinical response to TWO preferred medications, including a trial of at least 14 days with one medication requiring step therapy *

OR

1.2 Patient has ONE of the following:

- Allergy to preferred* medications
- Contraindication to all preferred* medications
- History of unacceptable/toxic side effects to at least two preferred* medications

Notes	*OH PDL: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Aimovig, Emgality, Ajovy

Diagnosis	Migraine Prophylaxis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following

1.1 Diagnosis of episodic migraine, with BOTH of the following

- 4-15 headaches per 30 days measured over 90 consecutive days
- Headache duration of longer than 4 hours per day or longer during an attack on average

OR

1.2 Diagnosis of chronic migraine, with BOTH of the following

- 15 or more headaches per 30 days measured over 90 consecutive days
- Headache duration of longer than 4 hours per day or longer during an attack on average

AND

2 - Trial and failure (at least 30 days each), contraindication, or intolerance to at least THREE controller migraine medications (i.e., beta-blockers, anticonvulsants, tricyclic antidepressants, and/or serotonin-norepinephrine)

AND

3 - Documentation of severity, frequency, and number of headache days per month (e.g., a headache diary)

AND

4 - If the request is for Emgality, the patient has had an inadequate clinical response or intolerance to a 30 day trial of ONE preferred* medication, which requires step therapy

AND

5 - If the request is for Aimovig at a dose of 140mg, Aimovig 70mg once monthly must have failed to provide adequate relief over two consecutive months

AND

6 - If the request is for Ajovy at a dose of 675mg (quarterly administration), the patient has demonstrated efficacy of Ajovy for at least 90 days

Notes	OH PDL: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Nurtec ODT, Qulipta	
Diagnosis	Migraine Prophylaxis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of episodic migraine, with BOTH of the following

- 4-15 headaches per 30 days measured over 90 consecutive days
- Headache duration of longer than 4 hours per day or longer during an attack on average

AND

2 - Trial and failure (at least 30 days each), contraindication, or intolerance to at least THREE controller migraine medications (i.e., beta-blockers, anticonvulsants, tricyclic antidepressants, and/or serotonin-norepinephrine reuptake inhibitors)

AND

3 - Patient has had an inadequate clinical response or intolerance to a 30-day trial of ONE preferred* medication, which requires step therapy

AND

4 - Documentation of severity, frequency, and number of headache days per month (e.g., a headache diary)

Notes	OH PDL: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Aimovig, Emgality, Ajovy, Nurtec, Qulipta	
Diagnosis	Migraine Prophylaxis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Evidence of improved headache control, such as a headache diary or documentation of severity, frequency, and number of headache days per month

AND

2 - If the request is for Ajovy at a dose of 675mg (quarterly administration), the patient has demonstrated efficacy of Ajovy for at least 90 days

AND

3 - If the request is for Aimovig at a dose of 140mg, Aimovig 70mg once monthly must have failed to provide adequate relief over two consecutive months

Product Name: Emgality	
Diagnosis	Episodic Cluster Headache
Approval Length	6 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 5 attacks within 30 days

AND

1.2 Attacks have a frequency between one every other day and eight per day; during part (but less than half) of the active time-course of cluster headache, attacks may be less frequent

AND

2 - Attacks characterized by severe or very severe unilateral orbital, supraorbital and/or temporal pain lasting 15 to 180 minutes when untreated; during part (but less than half) of the time-course of cluster headache, attacks may be less severe and/or of shorter or longer duration

AND

3 - ONE of the following:

3.1 ONE of the following symptoms or signs ipsilateral to the headache:

- Conjunctival injection and/or lacrimation
- Nasal congestion and/or rhinorrhea
- Eyelid edema
- Forehead and facial sweating
- Miosis and/or ptosis

OR

3.2 A sense of restlessness or agitation

AND

4 - At least two cluster periods lasting from seven days to one year (when untreated) and separated by pain-free remission periods of 90 days or more

AND

5 - Not better accounted for by another International Classification of Headache Disorders 3rd edition (ICHD-3) diagnosis

AND

6 - Failure or intolerance to verapamil titrated to at least a dose of 480 milligrams daily (Note: may need to be combined with glucocorticoids as adjunctive therapy for more rapid relief until verapamil is titrated)

2 . Revision History

Date	Notes
7/15/2022	Removed extra "or' in step 1 of Migraine Prophylaxis reauth

Prior Authorization Guideline

GL-99033 Central Nervous System (CNS) Agents - Anticonvulsants and Neuropathic Pain

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: brand Neurontin, brand Tegretol, brand Tegretol XR, brand Trileptal	
Diagnosis	Seizures*
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient is new to plan and has been established on the medication within the previous 120 days	

OR

2 - The patient cannot be changed to a preferred medication due to ONE of the following reasons:

2.1 Allergy to TWO preferred medications*

OR

2.2 Contraindication to or drug interaction with TWO preferred medications*

OR

2.3 History of unacceptable/toxic side effects to TWO preferred medications*

OR

3 - ONE of the following:

3.1 There has been a therapeutic failure to no less than TWO preferred products for a 30 day trial each*

OR

3.2 ALL of the following:

3.2.1 Prescription is submitted with the prescriber national provider identifier (NPI) of a physician who has registered a neurology specialty with Ohio Medicaid

AND

3.2.2 The request is for a standard tablet/capsule dosage form and is NOT a brand product with available generic alternatives

AND

3.2.3 Product is used only for seizures

AND

3.2.4 There has been a therapeutic failure to a trial of ONE preferred product for 30 days*

Notes	*Applies to Central Nervous System (CNS) Agents: Anticonvulsants. PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: brand Neurontin, brand Tegretol, brand Tegretol XR, brand Trileptal	
Diagnosis	Neuropathic Pain*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has had a therapeutic failure to no less than a 30-day trial of at least TWO preferred medications in separate pharmacologic classes

OR

2 - ONE of the following*:

2.1 Patient has allergy to preferred medications

OR

2.2 Patient has a contraindication to or drug interaction with preferred medications

OR

2.3 Patient has a history of unacceptable/toxic side effects to preferred medications	
Notes	*Applies to Central Nervous System (CNS) Agents: Neuropathic Pain. PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html

2 . Revision History

Date	Notes
11/30/2021	Removed step 2.4 in Anticonvulsant criteria

Prior Authorization Guideline

GL-99058 Central Nervous System (CNS) Agents - Anticonvulsants Rescue

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: Generic diazepam rectal gel	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - If the request is for a non-preferred medication*, the patient cannot be changed to a preferred medication due to ONE of the following:

1.1 Allergy to preferred medications

OR **1.2** Contraindication to or drug interaction with preferred medications **OR** **1.3** History of unacceptable/toxic side effects to preferred medications
Notes | *PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Valtoco	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient is 6 years of age or older	

Product Name: Nayzilam	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient is 12 years of age or older	

2 . Revision History

Date	Notes
12/1/2021	New guideline

Prior Authorization Guideline

GL-81233 Central Nervous System (CNS) Agents - Antidepressants

Formulary

Formulary Note

Guideline Note:

Effective Date:	4/1/2021

1 . Criteria

Product Name: Brand Brisdelle, generic paroxetine 7.5 mg, generic fluoxetine ER, generic fluvoxamine ER, Brand Paxil CR, generic paroxetine ER, Pexeva, Brand Khedezla, generic desvenlafaxine ER, Brand Pristiq, Drizalma, Fetzima, generic venlafaxine ER, Brand Aplenzin, Brand Forfivo XL, generic bupropion ER (XL), Emsam, Marplan, Brand Nardil, generic phenelzine, generic trazodone 300mg tab, Trintellix, Viibryd, Drizalma Sprinkle, generic clomipramine, Brand Anafranil, generic fluoxetine 60 mg, Brand Wellbutrin SR, Brand Wellbutrin XL, Brand Celexa, Brand Lexapro, Brand Remeron and Soltab, Brand Zoloft, Brand Parnate	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Patient is new to plan and has been established on the medication within the previous 120 days*

OR

2 - The medication is in the standard tablet or capsule dosage form and prescribed by a physician who is registered with Ohio Medicaid as having a specialty in psychiatry. (Other dosage forms may still require prior authorization by a psychiatrist.)

OR

3 - Therapeutic failure to TWO preferred** products for a 30-day trial each

OR

4 - The patient cannot be changed to a preferred** medication due to ONE of the following reasons:

- Allergy to preferred medications
- Contraindication to or drug interaction with preferred medications
- History of unacceptable/toxic side effects to preferred medications
- For orally disintegrating tablet dosage forms, the patient is unable or unwilling to swallow the standard tablet/capsule dosage form
- The requested medication's corresponding generic (if covered by the state) has been attempted and failed or is contraindicated

Notes	*Patients who have taken the drug in the previous 120 days, but do not have claims history (e.g. new to Medicaid), will be approved for PA after prescriber contact. **Ohio PDL: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
2/17/2021	Updated linked drugs, removed duloxetine for its own separate guideline.

Prior Authorization Guideline

GL-103852 Central Nervous System (CNS) Agents - Attention Deficit Hyperactivity Disorder Agents

Formulary

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Brand Evekeo, generic amphetamine sulfate tablet, Evekeo ODT, Brand Desoxyn, generic methamphetamine tablet, generic methylphenidate chewable tablet, Brand Zenzedi Tablet, Adhansia XR, Brand Kapvay, Jornay PM, generic methylphenidate ER (generic of Aptensio XR), Relexxi, generic methylphenidate ER (OSM) 72mg, Mydayis, Adzenys XR-ODT, Cotempla XR-ODT, Daytrana Patch, Dyanavel XR Suspension, Vyvanse chewable tablets, Brand Adderall tablets, Brand Adderall XR, Brand Intuniv, Brand Strattera, Azstarys	
Diagnosis	Non-Preferred Products
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - If for a non-preferred medication*, ONE of the following:

1.1 The patient failed a therapeutic trial of 14 days each of TWO preferred medications*

OR

1.2 Allergy to at least TWO preferred medications

OR

1.3 Contraindication to ALL preferred medications

OR

1.4 History of unacceptable/toxic side effects to TWO preferred medications

Notes	*https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP **Note: Short Acting considered separately from Long Acting products

Product Name: Brand Procentra, generic dextroamphetamine solution, Brand Methylin solution, generic methylphenidate solution	
Approval Length	12 month(s)
Guideline Type	Age Edit/Prior Authorization

Approval Criteria

1 - If the patient is 12 years of age or older, the patient has documentation of medical necessity for the use of the non-solid dosage form (e.g., inability to swallow tablets/capsules)

AND

2 - If for a non-preferred medication*, ONE of the following:

2.1 The patient failed a therapeutic trial of 14 days each of TWO preferred medications*

OR **2.2** Allergy to at least TWO preferred medications **OR** **2.3** Contraindication to ALL preferred medications **OR** **2.4** History of unacceptable/toxic side effects to TWO preferred medications

Notes	*https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP **Note: Short Acting considered separately from Long Acting products

Product Name: Qelbree	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria **1** - Patient has had an inadequate clinical response to a 30 day trial each of TWO preferred medications*	
Notes	*https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP **Note: Short Acting considered separately from Long Acting products

2 . Revision History

Date	Notes
2/18/2022	Removed Quillivant and Quillichew. Updated note. Added Azstarys.

Prior Authorization Guideline

GL-77538 Central Nervous System (CNS) Agents - Movement Disorders

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2021

1 . Criteria

Product Name: Ingrezza, Austedo, Brand Xenazine, generic tetrabenazine	
Diagnosis	Tardive Dyskinesia
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Prescribed by a Neurologist or Psychiatrist	

AND **2** - Used for the treatment of Tardive Dyskinesia

Product Name: Austedo	
Diagnosis	Huntington's Disease
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Used for the treatment of Huntington's Disease **AND** **2** - The patient has failed to respond to maximally tolerated dose of tetrabenazine	

Product Name: Brand Xenazine, generic tetrabenazine	
Diagnosis	Huntington's Disease
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Used for the treatment of Huntington's Disease	

2 . Revision History

Date	Notes
11/30/2020	New program

Prior Authorization Guideline

GL-104190 Central Nervous System (CNS) Agents - Multiple Sclerosis

Formulary

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Extavia, generic Glatopa, generic glatiramer, Mavenclad, Plegridy, Brand Tecfidera, generic dimethyl fumarate (Mylan (00378) & Cipla (69097) manufacturers only), Vumerity, Bafiertam, Kesimpta, brand Ampyra, Ponvory	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Claims history is not available (e.g. new to Medicaid) AND the prescriber attests that the patient has taken the requested drug in the previous 120 days	

OR

2 - The patient cannot be changed to a preferred* medication due to ONE of the following acceptable reasons:

- Allergy to preferred medications
- Contraindication to or drug interaction with preferred medications
- History of unacceptable/toxic side effects to preferred medications

OR

3 - Patient has had therapeutic failure with a trial of at least 30 days with ONE preferred* medication

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html

Product Name: Mayzent	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following have been reviewed prior to initiation:

- Liver function tests (LFTS)
- Complete blood count (CBC)
- Ophthalmic examination
- Varicella zoster virus antibodies
- Electrocardiogram (ECG)

AND

2 - Patient is not CYP2C9*3*3 genotype

AND

3 - Dose does not exceed 2 mg/day (milligrams per day)

AND

4 - ONE of the following

4.1 Claims history is not available (e.g. new to Medicaid) AND the prescriber attests that the patient has taken the requested drug in the previous 120 days

OR

4.2 The patient cannot be changed to a preferred* medication due to ONE of the following acceptable reasons

- Allergy to preferred medications
- Contraindication to or drug interaction with preferred medications
- History of unacceptable/toxic side effects to preferred medications

OR

4.3 Patient has had therapeutic failure with a trial of at least 30 days with ONE preferred* medication

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html

2 . Revision History

Date	Notes
3/1/2022	Update

Prior Authorization Guideline

GL-81228 Central Nervous System (CNS) Agents - Neuropathic Pain

Formulary

Formulary Note

Guideline Note:

Effective Date:	4/1/2021

1 . Criteria

Product Name: Gralise, Lyrica CR, Ztlido, Brand Norpramin, Brand Gen7t, Brands of lidocaine patch, Brand Lidoderm, Brand Lidaflex, Brand Pamelor	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has had a therapeutic failure to no less than a 30-day trial of at least TWO preferred* medications in separate pharmacologic classes	

OR **2** - ONE of the following*: **2.1** Patient has allergy to preferred medications **OR** **2.2** Patient has a contraindication to or drug interaction with preferred medications **OR** **2.3** Patient has a history of unacceptable/toxic side effects to preferred medications

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html

2 . Revision History

Date	Notes
2/17/2021	Added brands of preferred products that are NP

Prior Authorization Guideline

GL-104502 Central Nervous System (CNS) Agents - Parkinson's Agents

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/1/2022

1 . Criteria

Product Name: Brand Azilect, generic rasagiline, Brand Tasmar, generic tolcapone, Xadago, Gocovri, Osmolex ER, Brand Mirapex ER, generic pramipexole ER, generic ropinirole ER, carbidopa/levodopa dispersible tablets, Rytary, Brand Stalevo; generic carbidopa/levodopa/entacapone, Zelapar, brand Lodosyn, brand Sinemet, brand Comtan, Ongentys	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - ONE of the following	

1.1 Patient has had a therapeutic failure to a 30-day trial of ONE preferred medication*

OR

1.2 Patient has allergy to preferred* medications

OR

1.3 Patient has a contraindication or drug interaction with preferred* medications

OR

1.4 Patient has a history of unacceptable/toxic side effects to preferred* medications

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html. Neupro has its own guideline.

Product Name: Inbrija, Nourianz, Brand Apokyn, generic apomorphine hcl, Kynmobi	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation that the patient has had a trial with one other medication indicated for the treatment of “off episodes” (e.g. dopamine agonist, COMT [catechol-O-methyltransferase] inhibitor, or MAO-B [monoamine oxidase] inhibitor)

AND

2 - ONE of the following:

2.1 Patient has had a therapeutic failure to a 30-day trial of ONE preferred medication *

OR **2.2** Patient has allergy to preferred* medications **OR** **2.3** Patient has a contraindication or drug interaction with preferred* medications **OR** **2.4** Patient has a history of unacceptable/toxic side effects to preferred* medications	
Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html. Neupro has its own guideline.

2 . Revision History

Date	Notes
3/8/2022	Removed inactive GPI's. Added generic apomorphine hcl . Updated criteria of first box.

Prior Authorization Guideline

GL-104502 Central Nervous System (CNS) Agents - Parkinson's Agents

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/1/2022

1 . Criteria

Product Name: Brand Azilect, generic rasagiline, Brand Tasmar, generic tolcapone, Xadago, Gocovri, Osmolex ER, Brand Mirapex ER, generic pramipexole ER, generic ropinirole ER, carbidopa/levodopa dispersible tablets, Rytary, Brand Stalevo; generic carbidopa/levodopa/entacapone, Zelapar, brand Lodosyn, brand Sinemet, brand Comtan, Ongentys	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - ONE of the following **1.1** Patient has had a therapeutic failure to a 30-day trial of ONE preferred medication*	

OR

1.2 Patient has allergy to preferred* medications

OR

1.3 Patient has a contraindication or drug interaction with preferred* medications

OR

1.4 Patient has a history of unacceptable/toxic side effects to preferred* medications

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html. Neupro has i ts own guideline.

Product Name: Inbrija, Nourianz, Brand Apokyn, generic apomorphine hcl, Kynmobi	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation that the patient has had a trial with one other medication indicated for the treatment of “off episodes” (e.g. dopamine agonist, COMT [catechol-O-methyltransferase] inhibitor, or MAO-B [monoamine oxidase] inhibitor)

AND

2 - ONE of the following:

2.1 Patient has had a therapeutic failure to a 30-day trial of ONE preferred medication *

OR

2.2 Patient has allergy to preferred* medications **OR** **2.3** Patient has a contraindication or drug interaction with preferred* medications **OR** **2.4** Patient has a history of unacceptable/toxic side effects to preferred* medications	
Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html. Neupro has its own guideline.

2 . Revision History

Date	Notes
3/8/2022	Removed inactive GPI's. Added generic apomorphine hcl . Updated criteria of first box.

Prior Authorization Guideline

GL-88169 Central Nervous System (CNS) Agents, Narcolepsy

Formulary

Formulary Note

Guideline Note:

Effective Date:	7/1/2021

1 . Criteria

Product Name: Sunosi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

1.1 Narcolepsy with excessive daytime sleepiness

OR

1.2 Obstructive sleep apnea with excessive daytime sleepiness

AND

2 - An inadequate response to or inability to tolerate a 30-day course of treatment with modafinil or armodafinil

AND

3 - An inadequate response to or inability to tolerate a 30-day course of treatment with a preferred methylphenidate or amphetamine product

Notes	https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html

Product Name: Wakix, Xyrem	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of narcolepsy with cataplexy

OR

1.2 ALL of the following:

1.2.1 Diagnosis of narcolepsy with excessive daytime sleepiness

AND

1.2.2 An inadequate response to or inability to tolerate a 30-day course of treatment with modafinil or armodafinil

AND

1.2.3 An inadequate response to or inability to tolerate a 30-day course of treatment with a preferred methylphenidate or amphetamine product

Notes	https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html

Product Name: Xywav	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following

1.1.1 Diagnosis of narcolepsy with cataplexy

AND

1.1.2 Sodium restriction with documented adherence to sodium restricted diet

OR

1.2 ALL of the following:

1.2.1 Diagnosis of narcolepsy with excessive daytime sleepiness

AND

1.2.2 An inadequate response to or inability to tolerate a 30-day course of treatment with modafinil or armodafinil

AND

1.2.3 An inadequate response to or inability to tolerate a 30-day course of treatment with a preferred methylphenidate or amphetamine product

AND

1.2.4 Sodium restriction with documented adherence to sodium restricted diet

Notes	https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html

Product Name: Sunosi, Wakix, Xyrem, Xywav	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Attestation that the patient's condition has improved while taking the requested medication

2 . Revision History

Date	Notes
6/10/2021	New guideline

Prior Authorization Guideline

GL-103997 Central Nervous System (CNS) Agents, Skeletal Muscle Relaxants, Non-Benzodiazepine

Formulary

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Brand Amrix; generic cyclobenzaprine er capsule; Brand Fexmid; generic cyclobenzaprine 7.5mg tablet; Brand Lorzone; generic chlorzoxazone 375 mg tablet; generic chlorzoxazone 750mg tablet; Brand Skelaxin; generic metaxalone; generic orphenadrine; generic Orphenadrine compound forte; Brand Zanaflex capsules; generic tizanidine capsules; Ozobax	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has ONE of the following:	

1.1 Patient has allergy to preferred medications

OR

1.2 Patient has a contraindication to or drug-to-drug interaction with preferred medications

OR

1.3 Patient has a history of unacceptable/toxic side effects to preferred medications

OR

1.4 Patient has failed a therapeutic trial of 30 days with one preferred medication*

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html

Product Name: Brand Soma; generic carisoprodol; Vanadom	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following:

1.1 Patient has allergy to preferred medications

OR

1.2 Patient has a contraindication to or drug-to-drug interaction with preferred medications

OR

1.3 Patient has a history of unacceptable/toxic side effects to preferred medications

OR **1.4** Patient has failed a therapeutic trial of 30 days with one preferred medication* **AND** **2** - Provider attests there is no other muscle relaxant or agent indicated to treat fibromyalgia, or any other musculoskeletal condition, that would serve the clinical needs of the patient	
Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html

2 . Revision History

Date	Notes
2/23/2022	Updated GL name to remove ":". Added Vanadom and Ozobax. Removed inactive products. Updated approval length to 12 months instead of 365 days.

Prior Authorization Guideline

GL-98993 Central Nervous System (CNS) Agents- Alzheimer's Agents

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: Aricept, generic doneprezil 23mg tablets, Namenda, Namenda XR, memantine ER, memantine solution, Namzaric, galantamine solution, rivastigmine patch, Razadyne ER	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Claims history is not available (e.g. new to Medicaid) AND the prescriber attests that the patient has taken the requested drug in the previous 120 days	

OR **2** - The patient cannot be changed to a preferred* medication due to ONE of the following acceptable reasons: • Allergy to preferred medications • Contraindication to or drug-to-drug interaction with preferred medications • History of unacceptable/toxic side effects to preferred medications **OR** **3** - Patient has failed a therapeutic trial of at least 30 days with at least TWO preferred* medications	
Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html

2 . Revision History

Date	Notes
11/30/2021	Updated GPI list to reflect new PDL. Updated criteria.

Prior Authorization Guideline

GL-103787 Central Nervous System (CNS) Agents- Atypical Antipsychotics

Formulary

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Brand Abilify, aripiprazole ODT, generic aripiprazole solution, Brand Clozaril, generic clozapine ODT, Brand Zyprexa, Brand Zyprexa Zydis, Zyprexa Relprevv, generic olanzapine ODT, generic paliperidone tablet, Rexulti, Versacloz, Vraylar, Caplyta, Secuado, Brand Symbyax, generic fluoxetine/ olanzapine, Brand Clozaril, Brand Seroquel, Brand Seroquel XR, generic asenapine sublingual tablet	
Diagnosis	Non-Preferred Products
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - The patient is new to the plan and has been established on the medication within the previous 120 days

OR

2 - The medication is in the standard tablet/capsule dosage form and prescribed by a physician who is registered with Ohio Medicaid as having a specialty in psychiatry (Other dosage forms may still require prior authorization by a psychiatrist)

OR

3 - ALL of the following

3.1 ONE of the following

3.1.1 There has been an inadequate clinical response to a 30 day trial of TWO preferred* or step therapy* medications

OR

3.1.2 ONE of the following

- Allergy to preferred* medications
- Contraindication to or drug interaction with preferred* medications
- History of unacceptable/toxic side effects to preferred* medications

AND

3.2 If the request is for an orally disintegrating tablet, the patient is unable or unwilling to swallow the standard tablet/capsule dosage form

AND

3.3 If the request is for the Brand name, the corresponding generic (if covered by the state) has been attempted and failed or is contraindicated

Notes	*https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Lybalvi	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient is new to the plan and has been established on the medication within the previous 120 days

OR

2 - The medication is in the standard tablet/capsule dosage form and prescribed by a physician who is registered with Ohio Medicaid as having a specialty in psychiatry (Other dosage forms may still require prior authorization by a psychiatrist)

OR

3 - ALL of the following

3.1 ONE of the following

3.1.1 There has been an inadequate clinical response to a 30 day trial of TWO preferred* or step therapy* medications

OR

3.1.2 ONE of the following

- Allergy to preferred* medications
- Contraindication to or drug interaction with preferred* medications
- History of unacceptable/toxic side effects to preferred* medications

AND

3.2 The patient is NOT using opioids

AND

3.3 The patient is NOT undergoing acute opioid withdrawal

Notes	*https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Invega Hafyera	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient is new to the plan and has been established on the medication within the previous 120 days

OR

2 - BOTH of the following

2.1 The patient cannot be changed to a preferred* medication due to ONE of the following

- Allergy to all preferred* medications
- Contraindication to or drug-to-drug interaction with preferred* medications
- History of unacceptable/toxic side effects to preferred* medications

AND

2.2 Patient has failed one of the following treatments

- 4 months of Invega Sustenna
- 3 months of Invega Trinza

Notes	*https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Latuda, Fanapt, Brand Saphris

Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - The patient is new to the plan and has been established on the medication within the previous 120 days

OR

2 - The medication is in the standard tablet/capsule dosage form and prescribed by a physician who is registered with Ohio Medicaid as having a specialty in psychiatry (Other dosage forms may still require prior authorization by a psychiatrist)

OR

3 - ONE of the following

3.1 There has been an inadequate clinical response to a 30 day trial of ONE preferred* medication

OR

3.2 ONE of the following

- Allergy to preferred* medications
- Contraindication to or drug interaction with preferred* medications
- History of unacceptable/toxic side effects to preferred* medications

OR

3.3 The request is for Latuda (Lurasidone), and the patient is pregnant

Notes	*https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Abilify MyCite

Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient is new to the plan and has been established on the medication within the previous 120 days

OR

2 - The medication is in the standard tablet/capsule dosage form and prescribed by a physician who is registered with Ohio Medicaid as having a specialty in psychiatry (Other dosage forms may still require prior authorization by a psychiatrist)

OR

3 - ALL of the following

3.1 Prescribed by a psychiatrist following an aripiprazole serum blood level draw indicating the need for further investigation of adherence

AND

3.2 ONE of the following

3.2.1 There has been an inadequate clinical response to a 30 day trial of TWO preferred* or step therapy* medications

OR

3.2.2 ONE of the following

- Allergy to preferred* medications
- Contraindication to or drug interaction with preferred* medications
- History of unacceptable/toxic side effects to preferred* medications

Notes	*https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Nuplazid	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient is new to the plan and has been established on the medication within the previous 120 days

OR

2 - The medication is prescribed by a physician with a neurology specialty to a patient with a history of an anti-Parkinson's agent

OR

3 - ALL of the following

3.1 The patient is diagnosed with Parkinson's disease and has psychotic symptoms (hallucinations and/or delusions) that started after Parkinson's diagnosis

AND

3.2 Psychotic symptoms are severe and frequent enough to warrant treatment with an antipsychotic

AND

3.3 Psychotic symptoms are not related to dementia or delirium

AND

3.4 Patient's other medications for Parkinson's disease have been reduced or adjusted and psychotic symptoms remain OR the patient is unable to tolerate adjustment of these other medications

AND

3.5 There has been an inadequate clinical response to a 30-day trial of either quetiapine or clozapine OR these therapies cannot be utilized

2 . Revision History

Date	Notes
2/17/2022	Added Lybalvi, Invega Hafyera. Updated GPI list and NP product na mes. Re-organized Nuplazid criteria

Prior Authorization Guideline

GL-99001 Central Nervous System (CNS) Agents- Sedative-Hypnotics, Non-Barbiturate

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: Belsomra, Lunesta, eszopiclone, zolpidem SL, zolpidem ER, Ambien CR, Ambien, Zolpimist, Rozerem, ramelteon, Silenor, generic doxepin tablets (generic for Silenor), Restoril (all strengths), generic temazepam 7.5mg and 22.5mg, Edluar, Dayvigo, Halcion	
Approval Length	180 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient cannot be changed to a preferred* medication due to ONE of the following acceptable reasons:

- Allergy to preferred medications

• Contraindication to or drug-to-drug interaction with preferred medications • History of unacceptable/toxic side effects to preferred medications **OR** **2** - Patient has had therapeutic failure to a trial of at least 10 days with at least TWO preferred* medications **OR** **3** - Patient has a history of addiction and the request is for a non-controlled medication	
Notes	NOTE: *PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html

2 . Revision History

Date	Notes
11/30/2021	Updated GPI list to reflect new PDL. Updated criteria.

Prior Authorization Guideline

GL-56668 Central Nervous System (CNS) Agents: Fibromyalgia Agents

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2020

1 . Criteria

Product Name: Savella	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following:

1.1 Allergy to two medications, in different classes below, not requiring prior approval:*

- Gabapentin
- Pregabalin

- Short- and/or long-acting opioids
- Skeletal muscle relaxants
- SNRIs (Serotonin and norepinephrine reuptake inhibitors)
- SSRIs (Selective serotonin reuptake inhibitors)
- Trazodone
- Tricyclic antidepressants

OR

1.2 Contraindication to all medications not requiring prior approval*

OR

1.3 History of unacceptable/toxic side effects to two medications, in different classes below, not requiring prior approval:*

- Gabapentin
- Pregabalin
- Short- and/or long-acting opioids
- Skeletal muscle relaxants
- SNRIs
- SSRIs
- Trazodone
- Tricyclic antidepressants

OR

2 - Patient has trial of agents from two of the following drug classes for 14 days each in the past 90 days (guidelines suggest use of multiple agents concurrently to manage the signs of fibromyalgia):

- Gabapentin
- Pregabalin
- Short- and/or long-acting opioids
- Skeletal muscle relaxants
- SNRIs
- SSRIs
- Trazodone
- Tricyclic antidepressants

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html

2 . Revision History

Date	Notes
11/11/2019	C&S Implementation

Prior Authorization Guideline

GL-56534 Cerdelga and Zavesca

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2020
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Cerdelga	
Diagnosis	Gaucher Disease Type 1
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of Gaucher disease type 1

AND

2 - Patient is ONE of the following as detected by a Food and Drug Administration (FDA)-cleared test:

- CYP2D6 extensive metabolizer
- CYP2D6 intermediate metabolizer
- CYP2D6 poor metabolizer

Product Name: Cerdelga	
Diagnosis	Gaucher Disease Type 1
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Brand Zavesca, generic miglustat	
Diagnosis	Mild to Moderate Type 1 Gaucher Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of mild to moderate type 1 Gaucher disease

AND

2 - Patient is unable to receive enzyme replacement therapy due to ONE of the following conditions:

2.1 Allergy or hypersensitivity to enzyme replacement therapy

OR

2.2 Poor venous access

OR

2.3 Unavailability of enzyme replacement therapy (e.g., Cerezyme, VPRIV)

Product Name: Brand Zavesca, generic miglustat	
Diagnosis	Mild to Moderate Type 1 Gaucher Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
11/6/2019	New Guideline.

Prior Authorization Guideline

GL-108421 Cholbam

Formulary

Formulary Note

Guideline Note:

Effective Date:	8/1/2022

1 . Criteria

Product Name: Cholbam	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of a bile acid synthesis disorder

AND

1.2 It is due to single enzyme defects

OR

2 - ALL of the following:

2.1 Diagnosis of peroxisomal disorders including Zellweger spectrum disorders

AND

2.2 Patient exhibits manifestations of liver disease, steatorrhea, or complications from decreased fat soluble vitamin absorption

AND

2.3 It is being used as adjunctive treatment

Product Name: Cholbam	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cholbam therapy as evidenced by improvement in liver function [e.g., aspartate aminotransferase (AST), alanine aminotransferase (ALT)]

Prior Authorization Guideline

GL-109290 Cometriq

Formulary

Formulary Note

Guideline Note:

Effective Date:	9/1/2022

1 . Criteria

Product Name: Cometriq	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of medullary carcinoma

OR

1.2 ALL of the following:

1.2.1 Diagnosis of ONE of the following:

- Follicular carcinoma
- Hürthle cell carcinoma
- Papillary carcinoma

AND

1.2.2 Disease is progressive after treatment with ONE of the following as confirmed by claims history or submission of medical records:

- Lenvima (lenvatinib)
- Nexavar (sorafenib)

AND

1.2.3 Disease is at least ONE of the following:

- Symptomatic iodine-refractory
- Unresectable locoregional recurrent or persistent disease
- Distant metastatic disease

Product Name: Cometriq	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Cometriq therapy

Product Name: Cometriq	
Diagnosis	Non-Small Cell Lung Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Positive for RET gene rearrangements

Product Name: Cometriq	
Diagnosis	Non-Small Cell Lung Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Cometriq therapy

Product Name: Cometriq	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Cometriq will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Cometriq	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cometriq therapy

2 . Revision History

Date	Notes
7/12/2022	Updated GPIs. Revised clinical criteria for thyroid carcinomas to align with NCCN indications.

Prior Authorization Guideline

GL-105750 Compounds and Bulk Powders

Formulary

Formulary Note

Guideline Note:

Effective Date:	6/1/2022

1 . Criteria

Product Name: Compounds or Bulk Powders	
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - The requested drug component is a covered medication

AND

2 - ONE of the following:

2.1 The requested drug component is to be administered for an FDA (Food and Drug Administration)-approved indication

OR

2.2 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

AND

3 - If a drug included in the compound requires prior authorization and/or step therapy, all drug specific clinical criteria must also be met

AND

4 - If the drug component is no longer available commercially, it must not have been withdrawn for safety reasons

AND

5 - ONE of the following:

5.1 A unique vehicle is required

OR

5.2 A unique dosage form is required for a commercially available product due to patient's age, weight, or inability to take a solid dosage form

OR

5.3 A unique formulation is required for a commercially available product due to an allergy or intolerance to an inactive ingredient in the commercially available product

OR

5.4 There is a shortage of the commercially available product per the FDA Drug Shortage database or the ASHP (American Society of Health-System Pharmacists) Current Drug Shortages tracking log

AND

6 - Coverage for compounds and bulk powders will NOT be approved for any of the following:

6.1 For topical compound preparations (e.g., creams, ointments, lotions, or gels to be applied to the skin for transdermal, transcutaneous, or any other topical route), if the requested compound contains any FDA approved ingredient that is not FDA approved for TOPICAL use (see Table 1 in Background section)

OR

6.2 If the requested compound contains topical fluticasone, topical fluticasone will NOT be approved unless both of the following are met:

6.2.1 Topical fluticasone is intended to treat a dermatologic condition (scar treatments are considered cosmetic and will not be covered)

AND

6.2.2 Patient has a contraindication to all commercially available topical fluticasone formulations

OR

6.3 Requested compound contains any ingredients when used for cosmetic purposes (see Table 2 in Background section)

OR

6.4 Requested compound contains any ingredient(s) which are on the FDA's Do Not Compound List (see Table 3 in Background section)

2 . Background

Benefit/Coverage/Program Information

Table 1: Example topical compound preparations that contain any FDA approved ingredient that are not FDA approved for TOPICAL use, including but NOT LIMITED TO the following:

(1) Ketamine

(2) Gabapentin

(3) Flurbiprofen (topical ophthalmic use not included)

(4) Ketoprofen

(5) Morphine

(6) Nabumetone

(7) Oxycodone

(8) Cyclobenzaprine

(9) Baclofen

(10) Tramadol

(11) Hydrocodone

(12) Meloxicam

(13) Amitriptyline

(14) Pentoxifylline

(15) Orphenadrine

(16) Piroxicam

(17) Levocetirizine

(18) Amantadine

(19) Oxytocin

(20) Sumatriptan

(21) Chorionic gonadotropin (human)

(22) Clomipramine

(23) Dexamethasone

(24) Hydromorphone

(25) Methadone

(26) Papaverine

(27) Mefenamic acid

(28) Promethazine

(29) Succimer DMSA

(30) Tizanidine

(31) Apomorphine

(32) Carbamazepine

(33) Ketorolac

(34) Dimercaptopropane-sulfonate

(35) Dimercaptosuccinic acid

(36) Duloxetine

(37) Fluoxetine

(38) Bromfenac (topical ophthalmic use not included)

(39) Nepafenac (topical ophthalmic use not included)

Table 2: Example compounds that contain ingredients for cosmetic purposes:

(1) Hydroquinone

(2) Acetyl hexapeptide-8

(3) Tocopheryl Acid Succinate

(4) PracaSil TM-Plus

(5) Chrysaderm Day Cream

(6) Chrysaderm Night Cream

(7) PCCA Spira-Wash

(8) Lipopen Ultra

(9) Versapro

(10) Fluticasone

(11) Mometasone

(12) Halobetasol

(13) Betamethasone

(14) Clobetasol

(15) Triamcinolone

(16) Minoxidil

(17) Tretinoin

(18) Dexamethasone

(19) Spironolactone

(20) Cycloserine

(21) Tamoxifen

(22) Sermorelin

(23) Mederma Cream

(24) PCCA Cosmetic HRT Base

(25) Sanare Scar Therapy Cream

(26) Scarcin Cream

(27) Apothederm

(28) Stera Cream

(29) Copasil

(30) Collagenase

(31) Arbutin Alpha

(32) Nourisil

(33) Freedom Cepapro

(34) Freedom Silomac Andydrous

(35) Retinaldehyde

(36) Apothederm

Table 3: Example ingredients on the FDA's Do Not Compound List:

(1) 3,3′,4′,5-tetrachlorosalicylanilide

(2) Adenosine phosphate

(3) Adrenal cortex

(4) Alatrofloxacin mesylate

(5) Aminopyrine

(6) Astemizole

(7) Azaribine

(8) Benoxaprofen

(9) Bithionol

(10) Camphorated oil

(11) Carbetapentane citrate

(12) Casein, iodinated

(13) Cerivastatin sodium

(14) Chlormadinone acetate

(15) Chloroform

(16) Cisapride

(17) Defenfluramine hydrochloride

(18) Diamthazole dihydrochloride

(19) Dibromsalan

(20) Dihydrostreptomycin sulfate

(21) Dipyrone

(22) Encainide hydrochloride

(23) Etretinate

(24) Fenfluramine hydrochloride

(25) Flosequinan

(26) Glycerol, iodinated

(27) Grepafloxacin

(28) Mepazine

(29) Metabromsalan

(30) Methapyrilene

(31) Methopholine

(32) Methoxyflurane

(33) Mibefradil dihydrochloride

(34) Nomifensine maleate

(35) Novobiocin sodium

(36) Oxyphenisatin acetate

(37) Oxyphenisatin

(38) Pemoline

(39) Pergolide mesylate

(40) Phenacetin

(41) Phenformin hydrochloride

(42) Phenylpropanolamine

(43) Pipamazine

(44) Potassium arsenite

(45) Propoxyphene

(46) Rapacuronium bromide

(47) Rofecoxib

(48) Sibutramine hydrochloride

(49) Sparteine sulfate

(50) Sulfadimethoxine

(51) Sweet spirits of nitre

(52) Tegaserod maleate

(53) Temafloxacin hydrochloride

(54) Terfenadine

(55) Ticrynafen

(56) Tribromsalan

(57) Trichloroethane

(58) Troglitazone

(59) Trovafloxacin mesylate:

(60) Urethane

(61) Valdecoxib

(62) Zomepirac sodium

3 . Revision History

Date	Notes
4/6/2022	Updated criteria requirement for unique vehicle needed. Defined AS HP.

Prior Authorization Guideline

GL-85265 Continuous Glucose Monitoring Systems (CGMS)

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/1/2021

1 . Criteria

Product Name: Continuous Glucose Monitoring Systems (CGMS)	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Provider attestation of ALL of the following:

1.1 ONE of the following:

1.1.1 Patient has history of reoccurring hypoglycemia

OR

1.1.2 Patient meets ALL of the following:

- Is on an insulin pump or on three or more insulin injections per day
- Monitor blood glucose four or more times per day
- Require insulin dose adjustment within the last 12 months

AND

1.2 Patient has completed, or currently enrolled in, a comprehensive diabetes education program

AND

1.3 Provider will monitor and review Continuous Glucose Monitoring Systems (CGMS) results during authorization period

AND

1.4 Patient has had an appointment with provider within the past 6 months

AND

1.5 If the request is for a non-preferred product, ONE of the following*:

1.5.1 If there are at least three preferred alternatives, the patient has a history of failure, contraindication or intolerance to at least THREE preferred alternatives (Prior trials of formulary/preferred drug list (PDL) alternatives must sufficiently demonstrate that the formulary/PDL alternatives are either ineffective or inappropriate at the time of the request)

OR

1.5.2 If there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products (Prior trials of

formulary/preferred drug list (PDL) alternatives must sufficiently demonstrate that the formulary/PDL alternatives are either ineffective or inappropriate at the time of the request)	
Notes	*Applies to Non-Preferred Drugs Policy. OH PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html

Product Name: Continuous Glucose Monitoring Systems (CGMS)	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Provider attestation indicating provider and patient continue to have ongoing discussions about Continuous Glucose Monitoring Systems (CGMS) results during authorization period

AND

2 - A copy of the patient's most recent CGMS ambulatory glucose profile, including percent sensor usage, is attached

AND

3 - If for replacement, the device is malfunctioning and out of warranty

2 . Revision History

Date	Notes
4/20/2021	New guideline

Prior Authorization Guideline

GL-108001 Copiktra

Formulary

Formulary Note

Guideline Note:

Effective Date:	8/1/2022

1 . Criteria

Product Name: Copiktra	
Diagnosis	Chronic Lymphocytic Leukemia (CLL) / Small Lymphocytic Lymphoma (SLL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)	

AND

2 - Disease is relapsed or refractory

AND

3 - ONE of the following:

3.1 Failure to at least two prior therapies for CLL/SLL confirmed by claims history or submitted medical records. Examples include, but not limited to, regimens consisting of: [Leukeran (chlorambucil), Gazyva (obinutuzumab), Arzerra (ofatumumab), Bendeka (bendamustine), Imbruvica (ibrutinib), Calquence (acalabrutinib), Venclexta (venetoclax), etc.].

OR

3.2 History of intolerance or contraindication to at least two prior therapies for CLL/SLL. Examples include, but not limited to, regimens consisting of: [Leukeran (chlorambucil), Gazyva (obinutuzumab), Arzerra (ofatumumab), Bendeka (bendamustine), Imbruvica (ibrutinib), Calquence (acalabrutinib), Venclexta (venetoclax), etc.]. (please specify intolerance or contraindication)

Product Name: Copiktra	
Diagnosis	Chronic Lymphocytic Leukemia (CLL) / Small Lymphocytic Lymphoma (SLL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Copiktra therapy

Product Name: Copiktra	
Diagnosis	T-cell Lymphomas

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Hepatosplenic T-cell lymphoma
- Breast implant-associated anaplastic large cell lymphoma
- Peripheral T-cell lymphomas

AND

2 - Disease is relapsed or refractory

AND

3 - ONE of the following:

3.1 Failure to at least two prior systemic therapies confirmed by claims history or submitted medical records.

OR

3.2 History of intolerance or contraindication to at least two prior systemic therapies (please specify intolerance or contraindication)

Product Name: Copiktra	
Diagnosis	T-cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Copiktra therapy

Product Name: Copiktra	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Copiktra will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	

Product Name: Copiktra	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Copiktra therapy	

2 . Revision History

Date	Notes
6/8/2022	Removed coverage for gastric and nongastric MALT lymphomas, spl enic marginal zone lymphoma, and nodal marginal zone lymphoma. Added coverage for T-cell lymphomas. Updated trial and failure lang uage. Updated background and references.

Prior Authorization Guideline

GL-89400 Copper Chelating Agents

Formulary

Formulary Note

Guideline Note:

Effective Date:	9/1/2021

1 . Criteria

Product Name: Brand Depen Titratab, generic penicillamine tablets	
Diagnosis	Severe active rheumatoid arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of severe active rheumatoid arthritis	

Product Name: Brand Depen Titratab, generic penicillamine tablets	
Diagnosis	Severe active rheumatoid arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Brand Depen Titratab, generic penicillamine tablets	
Diagnosis	Wilson’s disease, Cystinuria
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

- Wilson’s disease (i.e., hepatolenticular degeneration)
- Cystinuria

Product Name: Brand Cuprimine, generic penicillamine capsules	
Diagnosis	Wilson’s disease, Cystinuria, Severe active rheumatoid arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

- Wilson’s disease (i.e., hepatolenticular degeneration)
- Cystinuria

- Severe active rheumatoid arthritis

AND

2 - History of failure or intolerance to penicillamine tablets (generic Depen Titratab)

Product Name: Brand Cuprimine, generic penicillamine capsules	
Diagnosis	Wilson's disease, Cystinuria, Severe active rheumatoid arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Brand Syprine, generic trientine, generic Clovique	
Diagnosis	Wilson's disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration)

AND

2 - History of failure, contraindication, or intolerance to penicillamine tablets (generic Depen Titratab) or penicillamine capsules (generic Cuprimine)

Product Name: Brand Syprine, generic trientine, generic Clovique	
Diagnosis	Wilson's disease

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Prior Authorization Guideline

GL-99368 Cotellic

Formulary

Formulary Note

Guideline Note:

Effective Date:	2/1/2022

1 . Criteria

Product Name: Cotellic	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of melanoma	

AND

2 - Disease is ONE of the following:

- Unresectable
- Metastatic

AND

3 - Disease is positive for ONE of the following mutations:

- BRAF V600E
- BRAF V600K

AND

4 - Used in combination with Zelboraf (vemurafenib)

Product Name: Cotellic	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Central Nervous System (CNS) Cancer

AND

2 - Disease is metastatic, recurrent, progressive or in an inaccessible location

AND

3 - Disease is positive for ONE of the following mutations:

- BRAF V600E
- BRAF V600K

AND

4 - Used in combination with Zelboraf (vemurafenib)

Product Name: Cotellic	
Diagnosis	Melanoma, Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Cotellic therapy

AND

2 - Used in combination with Zelboraf (vemurafenib)

Product Name: Cotellic	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Langerhans Cell Histiocytosis

- Erdheim-Chester Disease
- Rosai-Dorfman Disease

AND

2 - ONE of the following:

- Mitogen-activated protein (MAP) kinase pathway mutation
- No detectable mutation
- Testing not available

Product Name: Cotellic	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Cotellic therapy

Product Name: Cotellic	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Cotellic will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Product Name: Cotellic	
Diagnosis	NCCN Recommended Regimen

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cotellic therapy.

2 . Revision History

Date	Notes
12/7/2021	Updates per NCCN recommendations to CNS cancer and histiocytic neoplasms.

Prior Authorization Guideline

GL-61939 Cough and Cold Opioids

Formulary

Formulary Note

Guideline Note:

Effective Date:	3/17/2020

1 . Criteria

Product Name: Hydromet, hydrocodone/homatropine syrup, hydrocodone/homatropine tabs, Z-Tuss AC, Tuzistra XR, Tussicaps, hydrocodone polst/chlorpheniramine polst ER susp, M-END PE, Poly-Tussin AC, Capcof, Pro-Red AC, Histex-AC, Maxi-Tuss CD, promethazine w/codeine, Promethazine VC/codeine, promethazine-phenylephrine-codeine, pseudoeph-chlorphen w/hydrocodone soln, Rydex, Mar-Cof BP, Ninjacof-XG, Coditussin AC, Mar-Cof GG, Trymine CG, Guiatuss AC, M-Clear WC, Cheratussin AC, Codeine/Guaifenesin, G Tussin AC, Guaiatussin AC, Guaifenesin AC, Guaifenesin/Codeine, Virtussin A/C, Lortuss EX, Coditussin DAC, Tunsel C, Guaifenesin DAC, Virtussin DAC, Tuxarin ER*	
Diagnosis	Doses Exceeding the 90 MME Cumulative Threshold
Approval Length	30 Day(s)
Guideline Type	Morphine Milligram Equivalents (MME) Reviews

Approval Criteria	
1 - The prescriber attests they are aware of patient's current opioid therapy and morphine milligram equivalent (MME) dose and feels the treatment with the requested product is medically necessary (See Table 1 in the Background section)	
Notes	*Note: Approval length will be issued for up to 30 days and the authori zation should be entered for the MME requested.

Product Name: Hydromet, hydrocodone/homatropine syrup, hydrocodone/homatropine tabs, Z-Tuss AC, Tuzistra XR, Tussicaps, hydrocodone polst/chlorpheniramine polst ER susp, M-END PE, Poly-Tussin AC, Capcof, Pro-Red AC, Histex-AC, Maxi-Tuss CD, promethazine w/codeine, Promethazine VC/codeine, promethazine-phenylephrine-codeine, pseudoeph-chlorphen w/hydrocodone soln, Rydex, Mar-Cof BP, Ninjacof-XG, Coditussin AC, Mar-Cof GG, Trymine CG, Guiatuss AC, M-Clear WC, Cheratussin AC, Codeine/Guaifenesin, G Tussin AC, Guaiatussin AC, Guaifenesin AC, Guaifenesin/Codeine, Virtussin A/C, Lortuss EX, Coditussin DAC, Tunsel C, Guaifenesin DAC, Virtussin DAC, Tuxarin ER	
Diagnosis	Patients Under the Age of 18 Years
Approval Length	30 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescriber attests they are aware of Food and Drug Administration (FDA) labeled contraindications regarding use of opioid containing cough and cold products in patients less than 18 years of age and feels the treatment with the requested product is medically necessary (Document rationale for use)

AND

2 - Patient does not have a comorbid condition that may impact respiratory depression (e.g., asthma or other chronic lung disease, sleep apnea, body mass index greater than 30)

AND

3 - Patient has tried and failed at least one non-opioid containing cough and cold remedy

Product Name: Hydromet, hydrocodone/homatropine syrup, hydrocodone/homatropine tabs, Z-Tuss AC, Tuzistra XR, Tussicaps, hydrocodone polst/chlorpheniramine polst ER susp, M-END PE, Poly-Tussin AC, Capcof, Pro-Red AC, Histex-AC, Maxi-Tuss CD, promethazine

w/codeine, Promethazine VC/codeine, promethazine-phenylephrine-codeine, pseudoeph-chlorphen w/hydrocodone soln, Rydex, Mar-Cof BP, Ninjacof-XG, Coditussin AC, Mar-Cof GG, Trymine CG, Guiatuss AC, M-Clear WC, Cheratussin AC, Codeine/Guaifenesin, G Tussin AC, Guaiatussin AC, Guaifenesin AC, Guaifenesin/Codeine, Virtussin A/C, Lortuss EX, Coditussin DAC, Tunsel C, Guaifenesin DAC, Virtussin DAC, Tuxarin ER*	
Diagnosis	Requests Exceeding 120mL per fill and/or 360mL per 30 days
Approval Length	30 Day(s)
Guideline Type	Quantity Limit
Approval Criteria **1** - Prescriber attests that a larger quantity is medically necessary **AND** **2** - The requested dose is within the Food and Drug Administration (FDA) maximum dose per day, where an FDA maximum dose per day exists (See Table 1 in the Background section)	
Notes	*Note: Authorization will be issued for up to 30 days and the authorization should be entered for the quantity requested.

Product Name: Hydromet, hydrocodone/homatropine tabs, Z-Tuss AC, Tuzistra XR, Tussicaps, hydrocodone polst/chlorpheniramine polst ER susp, M-END PE, Poly-Tussin AC, Capcof, Pro-Red AC, Histex-AC, Maxi-Tuss CD, Promethazine VC/codeine, pseudoeph-chlorphen w/hydrocodone soln, Rydex, Mar-Cof BP, Ninjacof-XG, Coditussin AC, Mar-Cof GG, Trymine CG, Guiatuss AC, M-Clear WC, Cheratussin AC, Guaiatussin AC, Guaifenesin AC, Guaifenesin/Codeine, Virtussin A/C, Lortuss EX, Coditussin DAC, Tunsel C, Guaifenesin DAC, Virtussin DAC, Tuxarin ER	
Diagnosis	Non-Preferred Products
Approval Length	30 Day(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - If the request is for a non-preferred medication the patient must have a history of failure, contraindication or intolerance to a trial of at least THREE preferred cough and cold products*	
Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Background

Benefit/Coverage/Program Information

Table 1. CDC Recommended Opioid Maximum Morphine Milligram Equivalents per Day*

Active Ingredient	FDA Label Max Daily Doses	90 MME Equivalent (mg/day) (non treatment naïve)
Morphine	None	90mg
Hydromorphone	None	22.5mg
Hydrocodone	None	90mg
Tapentadol	600mg IR products	225mg
Oxymorphone	None	30mg
Oxycodone	None	60mg
Codeine	360mg	600mg
Pentazocine	None	243mg
Tramadol	400mg IR products	900mg
Meperidine	600mg	900mg
Butorphanol	None	12.86mg
Opium	4 suppositories/day Deodorized tincture: 24mg/day Camphorated tincture: 16mg/day	90mg
Benzhydrocodone**	None	73.77mg
Levorphanol	None	8.18mg

*Doses are not considered equianalgesic and table does not represent a dose conversion chart.

**Morphine Milligram Equivalents is derived from the package insert.

Table 2 Coverage Criteria Information:

Cough and Cold Products

Cough and Cold Products

Quantity Limit Rules:

- 120mL/fill
- 360mL/30 days

Prior Authorization Guideline

GL-81236 Cymbalta (duloxetine)

Formulary

Formulary Note

Guideline Note:

Effective Date:	4/1/2021

1 . Criteria

Product Name: Brand Cymbalta, generic duloxetine 40 mg	
Diagnosis	Antidepressant*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is new to plan and has been established on the medication within the previous 120 days**

OR

2 - The medication is in the standard tablet or capsule dosage form and prescribed by a physician who is registered with Ohio Medicaid as having a specialty in psychiatry. (Other dosage forms may still require prior authorization by a psychiatrist.)

OR

3 - Therapeutic failure to TWO preferred*** products for a 30-day trial each

OR

4 - The patient cannot be changed to a preferred*** medication due to ONE of the following reasons:

- Allergy to preferred medications
- Contraindication to or drug interaction with preferred medications
- History of unacceptable/toxic side effects to preferred medications
- For orally disintegrating tablet dosage forms, the patient is unable or unwilling to swallow the standard tablet/capsule dosage form
- The requested medication's corresponding generic (if covered by the state) has been attempted and failed or is contraindicated

Notes	*This applies to the Central Nervous System (CNS) Agents - Antidepressants policy **Patients who have taken the drug in the previous 120 days, but do not have claims history (e.g. new to Medicaid), will be approved for PA after prescriber contact. ***PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html

Product Name: Brand Cymbalta	
Diagnosis	Neuropathic Pain*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has had a therapeutic failure to no less than a 30-day trial of at least TWO preferred* medications in separate pharmacologic classes **OR** **2** - ONE of the following**: **2.1** Patient has allergy to preferred medications **OR** **2.2** Patient has a contraindication to or drug interaction with preferred medications **OR** **2.3** Patient has a history of unacceptable/toxic side effects to preferred medications	
Notes	*This applies to the Central Nervous System (CNS) Agents - Neuropathic Pain policy **PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html

2 . Revision History

Date	Notes
2/17/2021	New

Prior Authorization Guideline

GL-77337 Cystaran, Cystadrops

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2021

1 . Criteria

Product Name: Cystaran, Cystadrops	
Diagnosis	Cystinosis
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of cystinosis	

2 . Revision History

Date	Notes
11/23/2020	Added Cystadrops

Prior Authorization Guideline

GL-108134 Daraprim

Formulary

Formulary Note

Guideline Note:

Effective Date:	8/1/2022

1 . Criteria

Product Name: Brand Daraprim, generic pyrimethamine	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Medical record documentation (e.g., chart notes) of ONE of the following:

1.1 Treatment of severe acquired toxoplasmosis, including toxoplasmic encephalitis

OR

1.2 Treatment of congenital toxoplasmosis

OR

1.3 Secondary prophylaxis of toxoplasmic encephalitis

OR

1.4 ALL of the following:

1.4.1 Primary Pneumocystis pneumonia (PCP) prophylaxis in human immunodeficiency virus (HIV)-infected patients or as secondary prophylaxis in HIV-infected patients who have been treated for an acute episode of Pneumocystis pneumonia

AND

1.4.2 Patient has experienced intolerance to prior prophylaxis with trimethoprim-sulfamethoxazole (TMP-SMX)

AND

1.4.3 ONE of the following:

1.4.3.1 Patient has been re-challenged with trimethoprim-sulfamethoxazole (TMP-SMX) using a desensitization protocol and is still unable to tolerate

OR

1.4.3.2 Evidence of moderately severe or life threatening-reaction to trimethoprim-sulfamethoxazole (TMP-SMX) in the past (e.g., toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome)

OR

1.5 ALL of the following:

1.5.1 Primary prophylaxis of toxoplasmic encephalitis

AND

1.5.2 Toxoplasma immunoglobulin G (IgG) positive

AND

1.5.3 CD4 (cluster of differentiation 4) less than or equal to 100 cells per mm^3 if initiating prophylaxis, or CD4 100-200 cells per mm^3 if reinstituting prophylaxis*

AND

1.5.4 Will be used in combination with dapsone or atovaquone

AND

1.5.5 Patient has experienced intolerance to prior prophylaxis with trimethoprim-sulfamethoxazole (TMP-SMX)

AND

1.5.6 ONE of the following:

1.5.6.1 Patient has been re-challenged with trimethoprim-sulfamethoxazole (TMP-SMX) using a desensitization protocol and is still unable to tolerate

OR

1.5.6.2 Evidence of moderately severe or life threatening-reaction to trimethoprim-

sulfamethoxazole (TMP-SMX) in the past (e.g., toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome)	
Notes	*Consider discontinuation of primary prophylaxis if CD4 greater than 200 cells/mm^3 for greater than 3 months after institution of combination antiretroviral therapy.

Prior Authorization Guideline

GL-81038 Daurismo

Formulary

Formulary Note

Guideline Note:

Effective Date:	4/1/2021

1 . Criteria

Product Name: Daurismo	
Diagnosis	Acute Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of newly-diagnosed acute myeloid leukemia (AML)

OR

1.2 Relapsed/refractory disease with ALL of the following:

1.2.1 Given as a component of repeating the initial successful induction regimen

AND

1.2.2 Late relapse (greater than or equal to 12 months since induction regimen)

AND

1.2.3 Initial therapy was not administered continuously

AND

1.2.4 Initial therapy was not stopped due to development of clinical resistance

AND

2 - Daurismo therapy to be given in combination with low-dose cytarabine

AND

3 - One of the following:

3.1 Patient is at least 75 years old

OR

3.2 Patient has significant comorbidities that preclude the use of intensive induction chemotherapy [e.g., severe cardiac disease, Eastern Cooperative Oncology Group (ECOG) performance status greater than or equal to 2, baseline creatinine greater than 1.3 milligrams/deciliter]

Product Name: Daurismo	
Diagnosis	Acute Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Daurismo therapy

Product Name: Daurismo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Daurismo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Daurismo therapy

Prior Authorization Guideline

GL-104024 Dermatological - Topical Acne Products

Formulary

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Brand Tazorac cream & gel, generic tazarotene cream	
Diagnosis	Age 24 years and older*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of psoriasis

OR

1.2 Diagnosis of skin Cancer

OR

1.3 BOTH of the following:

1.3.1 Diagnosis of acne vulgaris

AND

1.3.2 History of a 30 day trial with an alternative therapy (benzoyl peroxide, sodium sulfacetamide or antibiotic) in the previous 90 days.**

Notes	*All topical retinoids require prior authorization for patients 24 years a nd older **PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Brand Differin (all formulations), generic adapalene (all formulations), Brand Retin-A, generic tretinoin, generic Avita, Brand Retin-A Micro, generic tretinoin microsphere, Brand Retin-A Micro pump, Altreno, Brand Atralin, Brand Epiduo, Brand Epiduo Forte, generic adapalene/benzoyl peroxide (generic of Epiduo/Epiduo Forte), Brand Fabior, generic tazarotene foam, adapalene pads, Brand Veltin, generic clindamycin/tretinoin (generic of Veltin), Ziana gel, Aklief, Arazlo	
Diagnosis	Age 24 years and older*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient has a diagnosis of skin cancer

OR

1.2 BOTH of the following:

1.2.1 Diagnosis of acne vulgaris

AND

1.2.2 History of a 30 day trial with an alternative therapy (benzoyl peroxide, sodium sulfacetamide or antibiotic) in the previous 90 days.**

Notes	*All topical retinoids require prior authorization for patients 24 years a nd older* **PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Clindacin Pac, Brand Evoclin, generic clindamycin foam, Brand Cleocin-T pads, generic clindamycin pledgets, generic Ery pads, generic erythromycin pads, Brand Aczone, generic dapsone (generic of Aczone), Brand Finacea, azelaic acid 15% (generic of Finacea), Brand Acanya, benzoyl peroxide foam (generic of Acanya), Brand Onexton, Brand Avar, Brand Avar LS, generic sodium sulfacetamide (generic of Avar and Avar LS), Brand Ovace Plus (all formulations), generic sodium sulfacetamide- sulfur (all formulations), adapalene cream, 0.3% gel (generic of Differin 0.3%), Altreno lotion, Brand Atralin gel, Brand Epiduo, Brand Epiduo Forte, adapalene/benzoyl peroxide gel (generic of Epiduo/Epiduo Forte), Brand Fabior, generic tazarotene foam, adapalene pads, Brand Veltin, clindamycin/tretinoin (generic of Veltin), Ziana gel, Brand Retin-A (all formulations and strengths), Brand Tazorac cream & gel, generic tazarotene cream, Amzeeq, Aklief, Arazlo, Winlevi

Diagnosis	Non-Preferred
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following (*See Preferred Drug List):

- Allergy to preferred medications
- Contraindication to, or drug interaction with, preferred medications
- History of unacceptable or toxic side effects to preferred medications

OR **2** - Inadequate response to a 30 day trial each of three preferred medications	
Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
2/23/2022	Added Winlevi, Finacea foam, generic Fabior, new dapsone strength and generic Epiduo forte. Updated Non-preferred trial language.

Prior Authorization Guideline

GL-107411 Dermatological Agents - Oral Acne Products

Formulary

Formulary Note

Guideline Note:

Effective Date:	7/1/2022

1 . Criteria

Product Name: Accutane, Amnesteem, Clavaris, Isotretinoin, Myorisan, Zenatane, Absorica, Absorica LD	
Approval Length	150 Days*
Guideline Type	Prior Authorization

Approval Criteria

1 - Medication is prescribed in accordance with its FDA approved labeling

AND

2 - Patient is registered and meets all of the requirements of the iPLEDGE program

AND

3 - Patient has failed a minimum 30-day trial with at least 1 topical FDA approved anti-acne product

AND

4 - Patient has failed a minimum 30-day trial with at least 1 oral FDA approved anti-acne product

AND

5 - Patient has not used oral tretinoin in the past 56 days

AND

6 - Patient has not been on an isotretinoin product in the past 56 days*

AND

7 - If the request is for a non-preferred** product, ONE of the following:

- Allergy to preferred medications
- Contraindication to or drug interaction to preferred medications
- History of unacceptable/toxic side effects to preferred medications

Notes	*Authorization for 150 days at a time, then patient must take 56 days off ** PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html

2 . Revision History

Date	Notes
5/23/2022	New guideline

Prior Authorization Guideline

GL-62866 Doptelet

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Doptelet	
Diagnosis	Thrombocytopenia in patients with chronic liver disease who are scheduled to undergo a procedure
Approval Length	1 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of thrombocytopenia	

AND

2 - Patient has chronic liver disease

AND

3 - Patient is scheduled to undergo a procedure

AND

4 - History of failure, contraindication, or intolerance to Mulpleta (lusutrombopag)

Product Name: Doptelet	
Diagnosis	Chronic Immune Thrombocytopenia (ITP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic immune thrombocytopenia (ITP)

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 History of failure, contraindication, or intolerance to at least ONE of the following:

- Corticosteroids
- Immunoglobulins

AND

2.1.2 History of failure, contraindication, or intolerance to Promacta (eltrombopag)

OR

2.2 Patient is currently on Doptelet therapy

Product Name: Doptelet	
Diagnosis	Chronic Immune Thrombocytopenia (ITP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Doptelet therapy

2 . Revision History

Date	Notes
3/9/2020	New Program

Prior Authorization Guideline

GL-82255 Egrifta

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/1/2021

1 . Criteria

Product Name: Egrifta SV	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of human immunodeficiency virus (HIV)-associated lipodystrophy	

2 . Revision History

Date	Notes
3/8/2021	Updated GPI’s and product name list.

Prior Authorization Guideline

GL-62873 Elmiron

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Elmiron	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has a documented diagnosis of bladder pain or discomfort associated with interstitial cystitis	

2 . Revision History

Date	Notes
3/5/2020	New Program

Prior Authorization Guideline

GL-96698 Emflaza

Formulary

Formulary Note

Guideline Note:

Effective Date:	12/1/2021

1 . Criteria

Product Name: Emflaza	
Diagnosis	Duchenne Muscular Dystrophy
Guideline Type	Prior Authorization

Approval Criteria

1 - Published clinical evidence shows Emflaza is likely to produce equivalent therapeutic results as other available corticosteroids (e.g. prednisone); therefore, Emflaza is not medically necessary for treatment of Duchenne muscular dystrophy. All requests for authorization will be denied by OptumRx and must be submitted through the appeals process to the UnitedHealthcare Community Plan Pharmacy Appeals team for consideration.

2 . Revision History

Date	Notes
10/14/2021	Added denial criteria/direction for OptumRx

Prior Authorization Guideline

GL-90007 Empaveli

Formulary

Formulary Note

Guideline Note:

Effective Date:	10/1/2021

1 . Criteria

Product Name: Empaveli	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting the diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) as confirmed by BOTH of the following:

1.1 Flow cytometry analysis confirming presence of PNH clones

AND

1.2 Laboratory results, signs, and/or symptoms attributed to PNH (e.g., abdominal pain, anemia, dyspnea, extreme fatigue, smooth muscle dystonia, unexplained/unusual thrombosis, hemolysis/hemoglobinuria, kidney disease, pulmonary hypertension, etc.)

AND

2 - ONE of the following:

2.1 Patient is not receiving Empaveli in combination with another complement inhibitor used for the treatment of PNH (e.g., Soliris, Ultomiris)

OR

2.2 ONE of the following:

2.2.1 Patient is currently receiving Soliris (eculizumab), which will be discontinued after an initial 4 week overlap period with Empaveli

OR

2.2.2 Patient is currently receiving Ultomiris (ravulizumab-cwvz), which will be stopped, and Empaveli will be initiated no more than 4 weeks after the last dose

AND

3 - Prescribed by or in consultation with ONE of the following:

- Hematologist
- Oncologist

Product Name: Empaveli	
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Empaveli therapy [e.g., increased or stabilization of hemoglobin levels, reduction in transfusions, improvement in hemolysis, decrease in LDH (lactate dehydrogenase), increased reticulocyte count, etc.]

AND

2 - Patient is not receiving Empaveli in combination with another complement inhibitor used for the treatment of paroxysmal nocturnal hemoglobinuria (PNH) (e.g., Soliris, Ultomiris)

AND

3 - Prescribed by or in consultation with ONE of the following:

- Hematologist
- Oncologist

Prior Authorization Guideline

GL-62827 Endari

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Endari	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

- Diagnosis of sickle cell disease

- Used to reduce acute complications of sickle cell disease

AND

2 - ONE of the following:

- Patient is using Endari with concurrent hydroxyurea therapy
- Patient is unable to take hydroxyurea due to a contraindication or intolerance

AND

3 - Patient has had 2 or more painful sickle cell crises within the past 12 months

Product Name: Endari	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Endari therapy

2 . Revision History

Date	Notes
3/5/2020	C&S Implementation

Prior Authorization Guideline

GL-103791 Endocrine Agents - Androgens

Formulary

Formulary Note

Guideline Note:

Effective Date:	2/16/2022

1 . Criteria

Product Name: methyltestosterone cap, Methitest, Brand Depo-Testosterone, generic testosterone cypionate inj, generic testosterone enanthate inj, Xyosted, Brand Androgel, generic testosterone gel/pump 1.62%, Brand Fortesta, generic testosterone gel 10mg/act, testosterone topical solution, Natesto, Brand Vogelxo, generic testosterone gel pump, Androderm Patch, Brand Androgel 1%, Brand Vogelxo 1%, Brand Testim 1%, generic testosterone gel 1%, Jatenzo	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient is 18 years of age and older	

AND

2 - The requested medication is being used for a FDA (Food and Drug Administration) approved indication

AND

3 - Submission of lab work to support the need for testosterone supplementation

AND

4 - If the request is for a non-preferred product ONE of the following: *

4.1 Patient has ONE of the following:

- Allergy to preferred medications
- Contraindication to, or drug interaction with, preferred medications
- History of unacceptable or toxic side effects to preferred medications

OR

4.2 Patient had a therapeutic failure to a 90 day trial of ALL preferred medications

Notes	*Ohio PDL Link: : https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
2/16/2022	Removed inactive GPI's. Added Patient is 18 years of age and older AND used for FDA approved indication.

Prior Authorization Guideline

GL-98775 Endocrine Agents - Diabetes - Hypoglycemia Treatments

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: Glucagon Emergency Kit (all manufacturers EXCEPT Lilly)	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 The patient and/or caregiver is unable to administer a preferred* glucagon product in a timely fashion

OR **1.2** Patient has ONE of the following*: **1.2.1** A trial with a preferred medication **OR** **1.2.2** An allergy to preferred medications **OR** **1.2.3** A contraindication to, or drug interaction with, preferred medications **OR** **1.2.4** A history of unacceptable/toxic side effects to preferred medications

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
11/24/2021	Update

Prior Authorization Guideline

GL-103995 Endocrine Agents - Diabetes - Non-Insulin

Formulary

Formulary Note

Guideline Note:

Effective Date:	3/1/2022

1 . Criteria

Product Name: Adlyxin, generic alogliptin, generic alogliptin/metformin, Bydureon BCise, generic pioglitazone-glimepiride, Invokamet XR, Jentadueto XR, Kombiglyze XR, metformin ER osmotic tabs (generic of Fortamet), Brand Glumetza, generic metformin ER modified release (generic for Glumetza), Brand Riomet, generic metformin soln, Onglyza, Ozempic, generic alogliptin/pioglitazone, Rybelsus, Segluromet, Steglatro, SymlinPen, Synjardy XR, Trijardy XR, Xigduo XR, Brand Nesina, Brand Kazano, Brand Duetact, Oseni, Brand Precose, Brand Actoplus Met, Brand Amaryl, Brand Actos, Brand Glucotrol XL, Brand Glynase	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Patient had a therapeutic failure of at least 60-day trial and failure with three preferred* products (inadequate clinical response after at least 60 days of recommended therapeutic dose with documented adherence to the regimen)

OR

2 - The patient cannot be changed to a preferred* medication within the same class due to ONE of the following reasons:

- Allergy to preferred medications not requiring prior authorization
- Contraindication to or drug interaction with preferred medications not requiring prior authorization
- History of unacceptable/toxic side effects to preferred medications not requiring prior authorization

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Glyxambi, Qtern, Steglujan	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient had no less than 90 days of at least one preferred* DPP-4 (dipeptidyl peptidase 4) and SGLT (sodium-glucose cotransporter) product

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Soliqua, Xultophy	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient had a therapeutic failure of at least 60-day trial and failure with three preferred* products (inadequate clinical response after at least 60 days of recommended therapeutic dose with documented adherence to the regimen)

OR

1.2 The patient cannot be changed to a preferred* medication within the same class due to ONE of the following reasons:

- Allergy to preferred medications
- Contraindication to or drug interaction with preferred medications
- History of unacceptable/toxic side effects to preferred medications

AND

2 - The request must address the patient's inability to use the individual components

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
2/28/2022	Added brand and generic Glumetza, brand Glucotrol XL and Brand Glynase.

Prior Authorization Guideline

GL-107474 Endocrine Agents - Growth Hormone

Formulary

Formulary Note

Guideline Note:

Effective Date:	7/1/2022

1 . Criteria

Product Name: Genotropin, Genotropin Miniquick, Nutropin AQ Nuspin, Saizen, Saizenprep Reconstitutionkit, Serostim, Zomacton, Norditropin Flexpro, Omnitrope, Humatrope, Skytrofa	
Diagnosis	Growth Hormone Deficiency (GHD) - Children
Approval Length	180 Day(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Standard deviation of 2.0 or more below mean height for chronological age	

AND

2 - Failure of any two stimuli test to raise the serum growth hormone level above 10 nanograms/milliliter

AND

3 - Patient is treated and followed by a pediatric endocrinologist, pediatric nephrologist, clinical geneticist, endocrinologist, or gastroenterologist (as appropriate for diagnosis)

AND

4 - All information and documentation requested on the prior authorization form to justify criteria being met, including ALL of the following, must be submitted:

- Height
- Weight
- Bone age (children)
- Date and result of most current x-ray
- Stimulus test results
- IGF-1 (insulin-like growth factor 1) levels
- Growth chart (children)

AND

5 - The patient does not have any FDA labeled contraindication(s) to therapy with the requested medication (i.e., closed epiphyses, no expanding intracranial lesion or tumor diagnosed, etc)

AND

6 - The requested medication will NOT be used in combination with another somatropin agent

AND

7 - If the request is non-preferred*, ONE of the following:

7.1 The patient cannot be changed to a preferred* medication due to ONE of the following:

- Allergy to preferred medications
- Contraindication to, or drug interaction with, preferred medications
- History of unacceptable/toxic side effects to preferred medications

OR

7.2 Patient has had a therapeutic failure to no less than a 90-day trial of at least ONE preferred* medication

OR

7.3 Patient has a medically valid reason for not being able to take a preferred* medication

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Genotropin, Genotropin Miniquick, Nutropin AQ Nuspin, Saizen, Saizenprep Reconstitutionkit, Serostim, Zomacton, Norditropin Flexpro, Omnitrope, Humatrope, Skytrofa	
Diagnosis	Growth Retardation of Chronic Kidney Disease - Children
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Standard deviation of 2.0 or more below mean height for chronological age

AND

2 - Irreversible renal insufficiency with a glomerular filtration rate less than 75 milliliters/minute per 1.73 square meters but pre-renal transplant

AND

3 - Patient is treated and followed by a pediatric endocrinologist, pediatric nephrologist, clinical geneticist, endocrinologist, or gastroenterologist (as appropriate for diagnosis)

AND

4 - All information and documentation requested on the prior authorization form to justify criteria being met, including ALL of the following, must be submitted:

- Height
- Weight
- Bone age (children)
- Date and result of most current x-ray
- Stimulus test results
- IGF-1 (insulin-like growth factor 1) levels
- Growth chart (children)

AND

5 - The patient does not have any FDA labeled contraindication(s) to therapy with the requested medication (i.e., closed epiphyses, no expanding intracranial lesion or tumor diagnosed, etc)

AND

6 - The requested medication will NOT be used in combination with another somatropin agent

AND

7 - If the request is non-preferred*, ONE of the following:

7.1 The patient cannot be changed to a preferred* medication due to ONE of the following:

- Allergy to preferred medications
- Contraindication to, or drug interaction with, preferred medications
- History of unacceptable/toxic side effects to preferred medications

OR

7.2 Patient has had a therapeutic failure to no less than a 90-day trial of at least ONE preferred* medication

OR

7.3 Patient has a medically valid reason for not being able to take a preferred* medication

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Genotropin, Genotropin Miniquick, Nutropin AQ Nuspin, Saizen, Saizenprep Reconstitutionkit, Serostim, Zomacton, Norditropin Flexpro, Omnitrope, Humatrope, Skytrofa	
Diagnosis	Krause-Kivlin Syndrome, Turner Syndrome, Prader-Willi Syndrome, Noonan Syndrome - Children
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

- Krause-Kivlin Syndrome
- Turner Syndrome
- Prader-Willi Syndrome
- Noonan Syndrome

AND

2 - Patient is treated and followed by a pediatric endocrinologist, pediatric nephrologist, clinical geneticist, endocrinologist, or gastroenterologist (as appropriate for diagnosis)

AND

3 - All information and documentation requested on the prior authorization form to justify criteria being met, including ALL of the following, must be submitted:

- Height
- Weight
- Bone age (children)
- Date and result of most current x-ray
- Stimulus test results
- IGF-1 (insulin-like growth factor 1) levels
- Growth chart (children)

AND

4 - The patient does not have any FDA labeled contraindication(s) to therapy with the requested medication (i.e., closed epiphyses, no expanding intracranial lesion or tumor diagnosed, etc)

AND

5 - The requested medication will NOT be used in combination with another somatropin agent

AND

6 - If the request is non-preferred*, ONE of the following:

6.1 The patient cannot be changed to a preferred* medication due to ONE of the following:

- Allergy to preferred medications
- Contraindication to, or drug interaction with, preferred medications
- History of unacceptable/toxic side effects to preferred medications

OR

6.2 Patient has had a therapeutic failure to no less than a 90-day trial of at least ONE preferred* medication

OR

6.3 Patient has a medically valid reason for not being able to take a preferred* medication

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Genotropin, Genotropin Miniquick, Nutropin AQ Nuspin, Saizen, Saizenprep Reconstitutionkit, Serostim, Zomacton, Norditropin Flexpro, Omnitrope, Humatrope, Skytrofa	
Diagnosis	Neurosecretory Growth Retardation - Children
Approval Length	180 Day(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Standard deviation of 2.0 or more below mean height for chronological age

AND

2 - Mixed or normal response to any 2 stimuli test in raising serum growth hormone above 10 nanograms/milliliter

AND

3 - Patient is treated and followed by a pediatric endocrinologist, pediatric nephrologist, clinical geneticist, endocrinologist, or gastroenterologist (as appropriate for diagnosis)

AND

4 - All information and documentation requested on the prior authorization form to justify criteria being met, including ALL of the following, must be submitted:

- Height
- Weight
- Bone age (children)
- Date and result of most current x-ray
- Stimulus test results
- IGF-1 (insulin-like growth factor 1) levels
- Growth chart (children)

AND

5 - The patient does not have any FDA labeled contraindication(s) to therapy with the requested medication (i.e., closed epiphyses, no expanding intracranial lesion or tumor diagnosed, etc)

AND

6 - The requested medication will NOT be used in combination with another somatropin agent

AND

7 - If the request is non-preferred*, ONE of the following:

7.1 The patient cannot be changed to a preferred* medication due to ONE of the following:

- Allergy to preferred medications
- Contraindication to, or drug interaction with, preferred medications
- History of unacceptable/toxic side effects to preferred medications

OR

7.2 Patient has had a therapeutic failure to no less than a 90-day trial of at least ONE preferred* medication

OR

7.3 Patient has a medically valid reason for not being able to take a preferred* medication

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Genotropin, Genotropin Miniquick, Nutropin AQ Nuspin, Saizen, Saizenprep Reconstitutionkit, Serostim, Zomacton, Norditropin Flexpro, Omnitrope, Humatrope, Skytrofa	
Diagnosis	Idiopathic Short Stature - Children
Approval Length	180 Day(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Standard deviation of 2.25 or more below mean height for chronological age

AND

2 - Mixed or normal response to any 2 stimuli tests in raising serum growth hormone above 10 nanograms/milliliter

AND

3 - Patient is treated and followed by a pediatric endocrinologist, pediatric nephrologist, clinical geneticist, endocrinologist, or gastroenterologist (as appropriate for diagnosis)

AND

4 - All information and documentation requested on the prior authorization form to justify criteria being met, including ALL of the following, must be submitted:

- Height
- Weight
- Bone age (children)
- Date and result of most current x-ray
- Stimulus test results
- IGF-1 (insulin-like growth factor 1) levels
- Growth chart (children)

AND

5 - The patient does not have any FDA labeled contraindication(s) to therapy with the requested medication (i.e., closed epiphyses, no expanding intracranial lesion or tumor diagnosed, etc)

AND

6 - The requested medication will NOT be used in combination with another somatropin agent

AND

7 - If the request is non-preferred*, ONE of the following:

7.1 The patient cannot be changed to a preferred* medication due to ONE of the following:

- Allergy to preferred medications
- Contraindication to, or drug interaction with, preferred medications
- History of unacceptable/toxic side effects to preferred medications

OR

7.2 Patient has had a therapeutic failure to no less than a 90-day trial of at least ONE preferred* medication

OR

7.3 Patient has a medically valid reason for not being able to take a preferred* medication

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Genotropin, Genotropin Miniquick, Nutropin AQ Nuspin, Saizen, Saizenprep Reconstitutionkit, Serostim, Zomacton, Norditropin Flexpro, Omnitrope, Humatrope, Skytrofa	
Diagnosis	Small for Gestational Age (SGA) - Children
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation to support diagnosis defined as birth weight or length 2 or more standard deviations below the mean for gestational age

AND

2 - The patient fails to manifest catch up growth before 2 years of age, defined as height 2 or more standard deviations below the mean for age and gender

AND

3 - Request includes the evaluation of growth curves from birth

AND

4 - Patient is treated and followed by a pediatric endocrinologist, pediatric nephrologist, clinical geneticist, endocrinologist, or gastroenterologist (as appropriate for diagnosis)

AND

5 - All information and documentation requested on the prior authorization form to justify criteria being met, including ALL of the following, must be submitted:

- Height
- Weight
- Bone age (children)
- Date and result of most current x-ray
- Stimulus test results
- IGF-1 (insulin-like growth factor 1) levels
- Growth chart (children)

AND

6 - The patient does not have any FDA labeled contraindication(s) to therapy with the requested medication (i.e., closed epiphyses, no expanding intracranial lesion or tumor diagnosed, etc)

AND

7 - The requested medication will NOT be used in combination with another somatropin agent

AND

8 - If the request is non-preferred*, ONE of the following:

8.1 The patient cannot be changed to a preferred* medication due to ONE of the following:

- Allergy to preferred medications
- Contraindication to, or drug interaction with, preferred medications
- History of unacceptable/toxic side effects to preferred medications

OR

8.2 Patient has had a therapeutic failure to no less than a 90-day trial of at least ONE preferred* medication

OR

8.3 Patient has a medically valid reason for not being able to take a preferred* medication

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Genotropin, Genotropin Miniquick, Nutropin AQ Nuspin, Saizen, Saizenprep Reconstitutionkit, Serostim, Zomacton, Norditropin Flexpro, Omnitrope, Humatrope, Skytrofa	
Diagnosis	Children
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation that the patient's health status has improved since last approval (i.e., height, weight gain, improved body composition)

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Genotropin, Genotropin Miniquick, Nutropin AQ Nuspin, Saizen, Saizenprep Reconstitutionkit, Serostim, Zomacton, Norditropin Flexpro, Omnitrope, Humatrope, Skytrofa	
Diagnosis	Growth Hormone Deficiency - Adult
Approval Length	180 Day(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Childhood onset, defined as a patient who was growth hormone deficient during childhood and who has a continued deficiency which is confirmed by provocative testing

OR

1.2 Adult onset, defined as a patient who has growth hormone deficiency, either alone or with multiple pituitary hormone deficiencies, such as hypopituitarism, as a result of pituitary disease, surgery, hypothalamic disease, radiation therapy, or trauma

AND

2 - Documentation of medical necessity from an endocrinologist

AND

3 - Biochemical diagnosis of growth hormone deficiency by means of a negative response to an appropriate stimulation test ordered by the endocrinologist (Clonidine test is not acceptable for adults)

AND

4 - There has been a baseline evaluation of ALL of the following clinical indicators:

- Insulin-like growth factor-1 (IGF-1)
- Fasting lipid profile
- BUN (Blood Urea Nitrogen)

- Fasting glucose
- Electrolyte levels
- Evaluation of any new osteoarthritis and joint pain
- Bone density test

AND

5 - The patient does not have any FDA labeled contraindication(s) to therapy with the requested medication (i.e., closed epiphyses, no expanding intracranial lesion or tumor diagnosed, etc)

AND

6 - Other hormonal deficiencies are addressed with adequate replacement therapy

AND

7 - The request does not exceed the maximum dose of ONE of the following:

- If patient is up to 35 years of age, less than or equal to 0.025 mg/kg (milligrams/kilogram) daily
- If patient is 35 years of age or older, less than or equal to 0.0125 mg/kg daily

AND

8 - If the request is non-preferred*, ONE of the following:

8.1 The patient cannot be changed to a preferred* medication due to ONE of the following:

- Allergy to preferred medications
- Contraindication to, or drug interaction with, preferred medications
- History of unacceptable/toxic side effects to preferred medications

OR

8.2 Patient has had a therapeutic failure to no less than a 90-day trial of at least ONE preferred* medication

OR **8.3** Patient has a medically valid reason for not being able to take a preferred* medication

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Genotropin, Genotropin Miniquick, Nutropin AQ Nuspin, Saizen, Saizenprep Reconstitutionkit, Serostim, Zomacton, Norditropin Flexpro, Omnitrope, Humatrope, Skytrofa	
Diagnosis	Adult
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation by endocrinologist that discontinuing the requested medication would have a detrimental effect on body composition or other metabolic parameters	
Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
5/25/2022	Added Skytrofa, updated GPI for Humatrope and Genotropin. Update d all diagnosis specific critiera to match PDL criteria

Prior Authorization Guideline

GL-99036 Endocrine Agents, Diabetes - Insulin

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: Admelog Solostar/inj, Basaglar, Semglee, Fiasp Flextouch/Penfill/inj, Humalog Kwikpen U-200, Humulin N Kwikpen/inj, Humulin R U-100, insulin glargine-YFGN, Lyumjev Kwikpen/inj, Novolin 70/30 Flexpen/Flexpen Relion/Relion/inj, Novolin N Flexpen/Flexpen Relion/Relion/inj, Novolin R Flexpen Relion/Flexpen/inj/Relion	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient cannot be changed to a preferred* medication due to ONE of the following*:

- Allergy to preferred medications

- Contraindication to, or drug interaction with, preferred medications
- History of unacceptable/toxic side effects to preferred medications
- Condition is difficult to control (i.e., prone to ketoacidosis, hypoglycemia)

OR

2 - Therapeutic failure to at least TWO preferred* medications within the same class, defined as the inability to reach A1C goal after at least 120 days of current regimen with documented adherence and appropriate dose escalation

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Tresiba Flextouch/inj	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient had an inadequate clinical response to at least ONE preferred* medication within the same class not requiring prior authorization, defined as the inability to reach A1C goal after at least 120 days of current regimen with documented adherence and appropriate dose escalation

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Afrezza	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient has a claim for a long-acting insulin in the previous 120 days

OR

1.2 Patient has type 2 diabetes

AND

2 - Patient has NOT been diagnosed with asthma nor COPD (chronic obstructive pulmonary disease)

AND

3 - Spirometry shows FEV1 (forced expiratory volume in 1 second) greater than or equal to 70% predicted

AND

4 - Patient has not smoked for at least 180 days

AND

5 - ONE of the following:

5.1 Patient cannot be changed to a preferred* medication due to ONE of the following*:

- Allergy to preferred medications
- Contraindication to, or drug interaction with, preferred medications
- History of unacceptable/toxic side effects to preferred medications
- Condition is difficult to control (i.e., prone to ketoacidosis, hypoglycemia)

OR

5.2 Therapeutic failure to at least TWO preferred* medications within the same class, defined as the inability to reach A1C goal after at least 120 days of current regimen with documented adherence and appropriate dose escalation

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
11/30/2021	Updated guideline name, drug list, and cleaned up criteria and notes.

Prior Authorization Guideline

GL-57227 Endocrine Agents: Estrogenic Agents

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2020

1 . Criteria

Product Name: Angeliq, generic estradiol/norethinrone acetate, Prefest, Duavee, Divigel, Elestrin, Estrasorb, Evamist, Menostar, Brand Minivelle, Femring, Brand Vagifem, generic estradiol vaginal tablet	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following (*See Preferred Drug List):

- Allergy to preferred medications
- Contraindication to, or drug interaction with, preferred medications

• History of unacceptable or toxic side effects to preferred medications **OR** **2** - Therapeutic failure to two trials, 30 days each, with preferred medications (*see Preferred Drug List)	
Notes	NOTE: *Ohio PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
11/26/2019	C&S Implementation

Prior Authorization Guideline

GL-77533 Endocrine Agents: Osteoporosis – Bone Ossification Enhancers

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2021

1 . Criteria

Product Name: alendronate oral soln, Brand Atelvia, generic risedronate delayed release, Binosto, etidronate, Fosamax Plus D, Brand Actonel, generic risedronate, calcitonin salmon nasal	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has failed a therapeutic trial of 90 days with one preferred medication within the same class of the requested medication*	

OR

2 - Patient has ONE of the following*:

2.1 An allergy to preferred medications

OR

2.2 A contraindication to, or drug interaction with, preferred medications

OR

2.3 A history of unacceptable or toxic side effects to preferred medications

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Tymlos	
Diagnosis	Osteoporosis
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient has failed a therapeutic trial of 90 days with one preferred medication within the same class of the requested medication*

OR

1.2 Patient has ONE of the following*:

1.2.1 An allergy to preferred medications

OR

1.2.2 A contraindication to, or drug interaction with, preferred medications

OR

1.2.3 A history of unacceptable or toxic side effects to preferred medications

AND

2 - All of the following:

2.1 Patient is female and postmenopausal

AND

2.2 Patient has a diagnosis of osteoporosis

AND

2.3 ONE of the following:

2.3.1 Patient has had a trial of bisphosphonates for greater than 365 days

OR

2.3.2 If bisphosphonates are contraindicated, patient has had a trial of calcitonin-salmon for greater than 730 days (2 years)

AND

2.4 Total lifetime therapy of parathyroid hormone analogs does not exceed 730 days (2 years)

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Forteo, Teriparatide	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient must not be at risk for osteosarcoma

AND

2 - Patient must have a history of fracture, multiple risk factors for fractures, or patient has failed or is intolerant to other therapy

AND

3 - ONE of the following:

3.1 Trial of bisphosphonates for greater than 365 days

OR

3.2 Bisphosphonates are contraindicated

AND

4 - Total lifetime therapy of parathyroid hormone analogs does not exceed 730 days (2 years)

AND

5 - If the request is for a non-preferred medication, ONE of the following:

5.1 Patient has failed a therapeutic trial of 90 days with one preferred medication within the same class of the requested medication* **OR** **5.2** Patient has ONE of the following*: **5.2.1** An allergy to preferred medications **OR** **5.2.2** A contraindication to, or drug interaction with, preferred medications **OR** **5.2.3** A history of unacceptable or toxic side effects to preferred medications	
Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
11/25/2020	Added Forteo and Teriparatide. Updated NP language.

Prior Authorization Guideline

GL-77533 Endocrine Agents: Osteoporosis – Bone Ossification Enhancers

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2021

1 . Criteria

Product Name: alendronate oral soln, Brand Atelvia, generic risedronate delayed release, Binosto, etidronate, Fosamax Plus D, Brand Actonel, generic risedronate, calcitonin salmon nasal	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has failed a therapeutic trial of 90 days with one preferred medication within the same class of the requested medication*

OR

2 - Patient has ONE of the following*:

2.1 An allergy to preferred medications

OR

2.2 A contraindication to, or drug interaction with, preferred medications

OR

2.3 A history of unacceptable or toxic side effects to preferred medications

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Tymlos	
Diagnosis	Osteoporosis
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient has failed a therapeutic trial of 90 days with one preferred medication within the same class of the requested medication*

OR

1.2 Patient has ONE of the following*:

1.2.1 An allergy to preferred medications

OR

1.2.2 A contraindication to, or drug interaction with, preferred medications

OR

1.2.3 A history of unacceptable or toxic side effects to preferred medications

AND

2 - All of the following:

2.1 Patient is female and postmenopausal

AND

2.2 Patient has a diagnosis of osteoporosis

AND

2.3 ONE of the following:

2.3.1 Patient has had a trial of bisphosphonates for greater than 365 days

OR

2.3.2 If bisphosphonates are contraindicated, patient has had a trial of calcitonin-salmon for greater than 730 days (2 years)

AND

2.4 Total lifetime therapy of parathyroid hormone analogs does not exceed 730 days (2 years)

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Forteo, Teriparatide

Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient must not be at risk for osteosarcoma

AND

2 - Patient must have a history of fracture, multiple risk factors for fractures, or patient has failed or is intolerant to other therapy

AND

3 - ONE of the following:

3.1 Trial of bisphosphonates for greater than 365 days

OR

3.2 Bisphosphonates are contraindicated

AND

4 - Total lifetime therapy of parathyroid hormone analogs does not exceed 730 days (2 years)

AND

5 - If the request is for a non-preferred medication, ONE of the following:

5.1 Patient has failed a therapeutic trial of 90 days with one preferred medication within the same class of the requested medication*

OR

5.2 Patient has ONE of the following*: **5.2.1** An allergy to preferred medications **OR** **5.2.2** A contraindication to, or drug interaction with, preferred medications **OR** **5.2.3** A history of unacceptable or toxic side effects to preferred medications	
Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
11/25/2020	Added Forteo and Teriparatide. Updated NP language.

Prior Authorization Guideline

GL-99035 Endocrine Agents: Endometriosis and Uterine Fibroids

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: Synarel	
Diagnosis	Endometriosis
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Therapeutic failure of a 30-day trial with BOTH of the following:

- A non-steroidal anti-inflammatory drug (NSAID)

- An oral contraceptive

AND

2 - ONE of the following*:

- Therapeutic failure of a 3-month trial of ONE preferred medication
- Allergy to preferred medications
- Contraindication to or drug-to-drug interaction with preferred medications
- History of unacceptable/toxic side effects to preferred medications

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP **These criteria refer to the Endocrine Agents: Endometriosis section of the PDL

Product Name: danazol, Depo-Subq Provera 104 mg, Lupron Depot 3.75 mg and 11.25 mg, Orilissa, Zoladex	
Diagnosis	Endometriosis
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Therapeutic failure of a 30-day trial with BOTH of the following:

- A non-steroidal anti-inflammatory drug (NSAID)
- An oral contraceptive

Notes	*These criteria refer to the Endocrine Agents: Endometriosis section o f the PDL

Product Name: Lupron Depot 3.75 mg and 11.25 mg, Oriahnn, Myfembree	
Diagnosis	Uterine Fibroids
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of uterine leiomyomas (fibroids)

AND

2 - Patient has failed a 90-day trial with an oral contraceptive

AND

3 - If the request is for a non-preferred medication ONE of the following*:

- Allergy to preferred medications
- Contraindication to or drug-to-drug interaction with preferred medications
- History of unacceptable/toxic side effects to preferred medications

AND

4 - ONE of the following:

4.1 If the request is for Oriahnn or Myfembree, treatment duration has not exceeded a total of 24 months

OR

4.2 If the request is for Lupron Depot 3.75mg or 11.25mg, treatment duration has not exceeded a total of 6 months

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP **These criteria refer to the Endocrine Agents: Uterine Fibroids section of the PDL

2 . Revision History

Date	Notes
12/1/2021	Update

Prior Authorization Guideline

GL-99035 Endocrine Agents: Endometriosis and Uterine Fibroids

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: Synarel	
Diagnosis	Endometriosis
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Therapeutic failure of a 30-day trial with BOTH of the following:

- A non-steroidal anti-inflammatory drug (NSAID)
- An oral contraceptive

AND

2 - ONE of the following*:

- Therapeutic failure of a 3-month trial of ONE preferred medication
- Allergy to preferred medications
- Contraindication to or drug-to-drug interaction with preferred medications
- History of unacceptable/toxic side effects to preferred medications

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP **These criteria refer to the Endocrine Agents: Endometriosis section of the PDL

Product Name: danazol, Depo-Subq Provera 104 mg, Lupron Depot 3.75 mg and 11.25 mg, Orilissa, Zoladex	
Diagnosis	Endometriosis
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Therapeutic failure of a 30-day trial with BOTH of the following:

- A non-steroidal anti-inflammatory drug (NSAID)
- An oral contraceptive

Notes	*These criteria refer to the Endocrine Agents: Endometriosis section o f the PDL

Product Name: Lupron Depot 3.75 mg and 11.25 mg, Oriahnn, Myfembree	
Diagnosis	Uterine Fibroids
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of uterine leiomyomas (fibroids)

AND

2 - Patient has failed a 90-day trial with an oral contraceptive

AND

3 - If the request is for a non-preferred medication ONE of the following*:

- Allergy to preferred medications
- Contraindication to or drug-to-drug interaction with preferred medications
- History of unacceptable/toxic side effects to preferred medications

AND

4 - ONE of the following:

4.1 If the request is for Oriahnn or Myfembree, treatment duration has not exceeded a total of 24 months

OR

4.2 If the request is for Lupron Depot 3.75mg or 11.25mg, treatment duration has not exceeded a total of 6 months

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP **These criteria refer to the Endocrine Agents: Uterine Fibroids section of the PDL

2 . Revision History

Date	Notes
12/1/2021	Update

Prior Authorization Guideline

GL-76696 Enspryng

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2021

1 . Criteria

Product Name: Enspryng	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of neuromyelitis optica spectrum disorder (NMOSD)

AND

2 - Patient has a positive serologic test for anti-aquaporin-4 (AQP4) antibodies

AND

3 - Patient is not receiving Enspryng in combination with any of the following:

- Disease modifying therapies for the treatment of multiple sclerosis [e.g., Gilenya (fingolimod), Tecfidera (dimethyl fumarate), Ocrevus (ocrelizumab), etc.]
- Complement inhibitors [e.g., Soliris (eculizumab)]
- Anti-IL6 (anti-interleukin-6) therapy [e.g., Actemra (tocilizumab)]
- B-cell depletion therapy [e.g. rituximab, Uplizna (inebilizumab)]

Product Name: Enspryng	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Enspryng therapy

AND

2 - Patient is not receiving Enspryng in combination with any of the following:

- Disease modifying therapies for the treatment of multiple sclerosis [e.g., Gilenya (fingolimod), Tecfidera (dimethyl fumarate), Ocrevus (ocrelizumab), etc.]
- Complement inhibitors [e.g., Soliris (eculizumab)]
- Anti-IL6 (anti-interleukin-6) therapy [e.g., Actemra (tocilizumab)]
- B-cell depletion therapy [e.g. rituximab, Uplizna (inebilizumab)]

2 . Revision History

Date	Notes
11/10/2020	New Program

Prior Authorization Guideline

GL-62846 Entocort

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Brand Entocort EC, generic budesonide DR	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Entocort EC is being used for the treatment of Crohn's disease	

2 . Revision History

Date	Notes
3/5/2020	C&S Implementation

Prior Authorization Guideline

GL-56562 Erivedge

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2020
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Erivedge	
Diagnosis	Basal cell carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - ONE of the following:

1.1 Diagnosis of metastatic basal cell carcinoma

OR

1.2 BOTH of the following:

1.2.1 Diagnosis of locally advanced basal cell carcinoma

AND

1.2.2 ONE of the following:

- Cancer has recurred following surgery
- Patient is not a candidate for surgery
- Patient is not a candidate for radiation

Product Name: Erivedge	
Diagnosis	Medulloblastoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of medulloblastoma

AND

2 - Patient has mutations in the sonic hedgehog pathway

AND

3 - Patient has failed prior chemotherapy

Product Name: Erivedge	
Diagnosis	Basal Cell Carcinoma, Medulloblastoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Erivedge therapy

Product Name: Erivedge	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Erivedge will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Product Name: Erivedge	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Erivedge therapy

2 . Revision History

Date	Notes
11/6/2019	New Guideline.

Prior Authorization Guideline

GL-57837 Erleada

Formulary

Formulary Note

Guideline Note:

Effective Date:	2/1/2020

1 . Criteria

Product Name: Erleada	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of prostate cancer	

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 Disease is castration-resistant or recurrent

AND

2.1.2 Disease is non-metastatic

OR

2.2 BOTH of the following:

2.2.1 Disease is castration-sensitive or naïve

AND

2.2.2 Disease is metastatic

AND

3 - ONE of the following:

3.1 Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g. Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

OR

3.2 Patient has had bilateral orchiectomy

Product Name: Erleada

Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Erleada therapy

Product Name: Erleada	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Erleada will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Product Name: Erleada	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Erleada therapy

2 . Revision History

Date	Notes

12/10/2019	C&S Implementation

Prior Authorization Guideline

GL-74975 Evrysdi

Formulary

Formulary Note

Guideline Note:

Effective Date:	10/9/2020

1 . Criteria

Product Name: Evrysdi	
Diagnosis	Spinal Muscular Atrophy (SMA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of spinal muscular atrophy (SMA)	

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) confirming the mutation or deletion of genes in chromosome 5q resulting in ONE of the following:

2.1 Homozygous gene deletion or mutation of SMN1 gene (e.g., homozygous deletion of exon 7 at locus 5q13)

OR

2.2 Compound heterozygous mutation of SMN1 gene [e.g., deletion of SMN1 exon 7 (allele 1) and mutation of SMN1 (allele 2)]

AND

3 - Patient is not dependent on invasive ventilation or tracheostomy

AND

4 - Patient is not dependent on the use of non-invasive ventilation beyond use for naps and nighttime sleep

AND

5 - Physician attests that Evrysdi is not to be initiated in a patient less than 2 months of age

AND

6 - Patient is not receiving concomitant chronic survival motor neuron (SMN)-modifying therapy [e.g., Spinraza (nusinersen)]

AND

7 - Patient has not previously received gene replacement therapy for the treatment of SMA [e.g., Zolgensma (onasemnogene abeparvovec-xioi)]

AND

8 - Submission of medical records (e.g., chart notes, laboratory values) documenting the baseline assessment of at least ONE of the following exams (based on patient age and motor ability) to establish baseline motor ability (baseline motor function analysis could include assessments evaluated prior to receipt of previous chronic SMN-modifying therapy if transitioning therapy)*:

- Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)
- Hammersmith Infant Neurological Exam Part 2 (HINE-2)
- Hammersmith Functional Motor Scale Expanded (HFMSE)
- Upper Limb Module (ULM) Test
- Motor Function Measure 32 (MFM-32) Scale

AND

9 - Prescribed by a neurologist with expertise in the treatment of SMA

Notes	*Baseline assessments for patients less than 2 months of age request ing Evrysdi proactively are not necessary in order not to delay access to initial therapy in recently diagnosed infants. Initial assessments sho rtly post-therapy can serve as baseline with respect to efficacy reauth orization assessment.

Product Name: Evrysdi	
Diagnosis	Spinal Muscular Atrophy (SMA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) with the most recent results documenting a positive clinical response to Evrysdi compared to pretreatment baseline status [inclusive of baseline assessments prior to receipt of previous chronic survival motor neuron (SMN)-modifying therapy] as demonstrated by at least ONE of the following exams:

1.1 Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND) with ONE of the following:

1.1.1 Improvement or maintenance of previous improvement of at least a 4-point increase in score from pretreatment baseline

OR

1.1.2 Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

OR

1.2 Hammersmith Infant Neurological Exam Part 2 (HINE-2) with ONE of the following:

1.2.1 Improvement or maintenance of previous improvement of at least a 2-point (or maximal score) increase in ability to kick

OR

1.2.2 Improvement or maintenance of previous improvement of at least a 1-point increase in any other HINE-2 milestone (e.g., head control, rolling, sitting, crawling, etc.), excluding voluntary grasp

OR

1.2.3 The patient exhibited improvement, or maintenance of previous improvement, in more HINE motor milestones than worsening, from pretreatment baseline (net positive improvement)

OR

1.2.4 Patient has achieved and maintained any new motor milestones when they would otherwise be unexpected to do so

OR

1.3 Hammersmith Functional Motor Scale Expanded (HFMSE) with ONE of the following:

1.3.1 Improvement or maintenance of previous improvement of at least a 3-point increase in score from pretreatment baseline

OR

1.3.2 Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

OR

1.4 Upper Limb Module (ULM) with ONE of the following:

1.4.1 Improvement or maintenance of previous improvement of at least a 2-point increase in score from pretreatment baseline

OR

1.4.2 Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

OR

1.5 Motor Function Measure 32 (MFM-32) with ONE of the following:

1.5.1 Improvement or maintenance of previous improvement of at least a 3-point increase in score from pretreatment baseline

OR

1.5.2 Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

AND

2 - Patient is not dependent on invasive ventilation or tracheostomy

AND

3 - Patient is not dependent on the use of non-invasive ventilation beyond use for naps and nighttime sleep

AND

4 - Patient is not receiving concomitant chronic SMN-modifying therapy [e.g., Spinraza (nusinersen)]

AND

5 - Patient has not previously received gene replacement therapy for the treatment of spinal muscular atrophy (SMA) [e.g., Zolgensma (onasemnogene abeparvovec-xioi)]

AND

6 - Prescribed by a neurologist with expertise in the treatment of SMA

Prior Authorization Guideline

GL-99817 Exkivity

Formulary

Formulary Note

Guideline Note:

Effective Date:	2/1/2022

1 . Criteria

Product Name: Exkivity	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of non-small cell lung cancer (NSCLC)	

AND

2 - Disease is locally advanced or metastatic

AND

3 - Disease is epidermal growth factor receptor (EGFR) exon 20 insertion mutation positive

AND

4 - Subsequent therapy for disease that has progressed on or after platinum-based chemotherapy

Product Name: Exkivity	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Exkivity therapy

Product Name: Exkivity	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Exkivity will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Exkivity	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Exkivity therapy

2 . Revision History

Date	Notes
12/8/2021	New guideline

Prior Authorization Guideline

GL-105781 Firdapse

Formulary

Formulary Note

Guideline Note:

Effective Date:	6/1/2022

1 . Criteria

Product Name: Firdapse	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS)	

AND

2 - Patient is not receiving Firdapse in combination with similar potassium channel blockers [e.g., Ampyra (dalfampridine)]

Product Name: Firdapse	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Firdapse therapy

AND

2 - Patient is not receiving Firdapse in combination with similar potassium channel blockers [e.g., Ampyra (dalfampridine)]

Prior Authorization Guideline

GL-88332 Fotivda

Formulary

Formulary Note

Guideline Note:

Effective Date:	8/1/2021

1 . Criteria

Product Name: Fotivda	
Diagnosis	Renal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced renal cell carcinoma (RCC)

AND

2 - ONE of the following:

- Disease has relapsed
- Disease is refractory

AND

3 - Patient has received two or more prior systemic therapies

Product Name: Fotivda	
Diagnosis	Renal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Fotivda therapy

Product Name: Fotivda	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Fotivda

Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Fotivda therapy

Prior Authorization Guideline

GL-62854 Galafold

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Galafold	
Diagnosis	Fabry disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Fabry disease	

AND

2 - Patient has an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data

AND

3 - Patient is not receiving Galafold in combination with Fabrazyme (agalsidase beta)

Product Name: Galafold	
Diagnosis	Fabry disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Galafold therapy

AND

2 - Patient is not receiving Galafold in combination with Fabrazyme (agalsidase beta)

2 . Revision History

Date	Notes
3/6/2020	C&S Implementation

Prior Authorization Guideline

GL-99071 Gastrointestinal Agents - Anti-Emetics

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: generic aprepitant 80 mg/therapy pack, Bonjesta, generic doxylamine/pyridoxine, metoclopramide ODT, Sancuso, Zuplenz, Brand Reglan, Brand Zofran, Brand Compro, Brand Promethegan, Brand Transderm-Scop	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has a therapeutic failure to no less than a 7-day trial on at least ONE preferred* medication	

OR **2** - Patient cannot be changed to a preferred* medication due to ONE of the following: • Allergy to preferred medications • Contraindication to, or drug interaction with, preferred medications • History of unacceptable/toxic side effects to preferred medications	
Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
11/30/2021	Updated guideline name, drug list, cleaned up criteria and note

Prior Authorization Guideline

GL-98785 Gastrointestinal Agents - Crohn's Disease

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: Ortikos	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following*

- An allergy to preferred medications
- A contraindication to, or drug interaction with, preferred medications
- A history of unacceptable or toxic side effects to preferred medications

OR **2** - Patient has had an inadequate clinical response to a 30 day trial each of two preferred medications*	
Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
12/1/2021	New

Prior Authorization Guideline

GL-104200 Gastrointestinal Agents - Pancreatic Enzymes

Formulary

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Pancreaze, Pertzye, Viokace	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient has had a therapeutic failure to a 14 day trial of one preferred medication*

OR **1.2** Patient has ONE of the following: **1.2.1** Patient has an allergy to preferred medications **OR** **1.2.2** Patient has a contraindication or drug interaction with preferred medications **OR** **1.2.3** Patient has a history of unacceptable/toxic side effects to preferred medications

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
3/1/2022	Updated GL name to remove ":" and updated Pancreaze GPI's and n ote

Prior Authorization Guideline

GL-104233 Gastrointestinal Agents - Ulcerative Colitis Agents

Formulary

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Dipentum, Brand Asacol HD, generic mesalamine DR 800mg (generic for Asacol HD), generic mesalamine DR 1.2g (generic for Lialda), Brand Canasa, generic mesalamine supp, Brand Delzicol, Brand Apriso, Brand Rowasa kit, Brand Uceris (foam and ER tab), Brand Colazal, Brand Azulfidine, Brand Azulfidine EN	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient cannot be changed to a preferred* medication due to ONE of the following acceptable reasons:

• An allergy to preferred medications • A contraindication to, or drug interaction with, preferred medications • A history of unacceptable or toxic side effects to preferred medications **OR** **2** - Patient has had an inadequate clinical response to a 30 day trial each of TWO preferred medications*

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
3/1/2022	Update

Prior Authorization Guideline

GL-104260 Gastrointestinal Agents, Proton Pump Inhibitors

Formulary

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Prilosec susp packet, Prilosec OTC tab, generic omeprazole tab, Brand Protonix tab, Brand Prevacid cap, Brand Prevacid solutab, generic lansoprazole orally disintegrating tab, Brand Nexium cap, generic esomeprazole cap, Brand Aciphex tab, generic rabeprazole tab, Brand Aciphex Sprinkle cap, generic rabeprazole sprinkle DR cap, Dexilant cap, Brand Zegerid OTC cap, generic omeprazole-sodium bicarbonate cap, generic esomeprazole susp packet, generic dexlansoprazole	
Diagnosis	Non-preferred medications
Approval Length	180 Day(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - ONE of the following for a non-preferred medication*:

1.1 Patient has failed a therapeutic trial of 30 days with two preferred medications*

OR

1.2 Patient has ONE of the following:*

- An allergy to preferred medications
- A contraindication to, or drug interaction with, preferred medications
- A history of unacceptable or toxic side effects to preferred medications
- Presence of a gastrostomy and-or jejunostomy tube (G-, GJ-, J-tube)

OR

1.3 The requested medication was initiated in the hospital for the treatment of a condition such as a GI (gastrointestinal) bleed

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Brand Protonix susp packet, generic pantoprazole susp packet	
Approval Length	180 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient is 6 years of age or under

OR

1.2 Patient is greater than 6 years of age and ONE of the following:

1.2.1 Patient has failed a therapeutic trial of 30 days with two preferred medications*

OR

1.2.2 Patient has ONE of the following:*

- An allergy to preferred medications
- A contraindication to, or drug interaction with, preferred medications
- A history of unacceptable or toxic side effects to preferred medications
- Presence of a gastrostomy and-or jejunostomy tube (G-, GJ-, J-tube)

OR

1.2.3 The requested medication was initiated in the hospital for the treatment of a condition such as a GI (gastrointestinal) bleed

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Preferred: generic omeprazole cap, generic pantoprazole tab, generic lansoprazole cap, Brand Nexium Granules susp packets, Brand Protonix susp packet. Non-Preferred: Prilosec susp packet, Prilosec OTC tab, generic omeprazole tab, Brand Protonix tab, Brand Prevacid cap, Brand Prevacid solutab, generic lansoprazole orally disintegrating tab, Brand Nexium cap, generic esomeprazole cap, Brand Aciphex tab, generic rabeprazole tab, Brand Aciphex Sprinkle cap, generic rabeprazole sprinkle DR cap, Dexilant cap, Brand Zegerid OTC cap, generic omeprazole-sodium bicarbonate cap, generic pantoprazole susp packet, generic esomeprazole susp packet, generic dexlansoprazole

Diagnosis	Doses greater than once daily*
Guideline Type	Quantity Limit

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Patient has a diagnosis of H.Pylori (Helicobacter pylori)**

AND

1.1.2 Dosing is twice daily

OR

1.2 BOTH of the following:

1.2.1 Patient has ONE of the following diagnoses:**

- COPD (chronic obstructive pulmonary disease)
- Dyspepsia
- Gastritis
- Gastroparesis
- Symptomatic Uncomplicated Barrett's Esophagus
- Carcinoma of GI tract
- Crest Syndro
- Esophageal Varices
- Scleroderma
- Systemic Mastocytosis
- Zollinger Ellison Syndrome

AND

1.2.2 Patient must have failed once daily dosing

Notes	*No PA needed for preferred PPI at any dose for age under 21 **Authorization length for H. Pylori is 30 days, all other 365 days

2 . Revision History

Date	Notes
3/2/2022	Added generic pantoprazole susp packet, generic esomeprazole susp packet and generic dexlansoprazole. Reformatted Protonix (pantoprazole) susp criteria. Added Gastritis to diagnosis list for QL section.

Prior Authorization Guideline

GL-104262 Gastrointestinal Agents: Irritable Bowel Syndrome (IBS) with Diarrhea

Formulary

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Generic alosetron, Brand Lotronex, Viberzi	
Diagnosis	Irritable Bowel Syndrome (IBS) with Diarrhea
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has had an inadequate clinical response to preferred* medications, including a 14-day trial of one medication which requires step therapy

OR **2** - Patient has ONE of the following: • Allergy to preferred medications • Contraindication to or drug interaction to preferred medications • History of unacceptable/toxic side effects to preferred medications	
Notes	* PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html

2 . Revision History

Date	Notes
3/2/2022	New Guideline

Prior Authorization Guideline

GL-104198 Gastrointestinal Agents: Unspecified GI

Formulary

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Movantik, Brand Amitiza, Linzess 145mcg & 290mcg capsule	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Patient has had an inadequate clinical response to a 14-day trial of TWO preferred* medications

AND

2 - Patient is 18 years of age or older	
Notes	*NOTE: PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html

Product Name: Linzess 72 mcg capsule, Motegrity, Trulance, Zelnorm, generic lubiprostone	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 18 years of age or older

AND

2 - One of the following

2.1 Patient has had an inadequate clinical response to a 14-day trial of THREE preferred* medications, including one which requires step therapy

OR

2.2 Patient has ONE of the following:

- Allergy to preferred medications
- Contraindication to or drug interaction to preferred medications
- History of unacceptable/toxic side effects to preferred medications

Notes	*NOTE: PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html

Product Name: Zorbtive, Gattex	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of short bowel syndrome (SBS)

AND

2 - Patient has evidence of specialized nutritional support

AND

3 - If the request is for Gattex, there must be evidence of parenteral nutrition support at least three times per week and appropriate colonoscopy and lab assessment (bilirubin, alkaline phosphatase, lipase, and amylase) 180 days prior to initiation

AND

4 - Patient is 18 years of age or older

Product Name: Zorbtive, Gattex	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has evidence of improved condition (i.e. as measured by total volume, total calories, or decreased frequency of specialized nutrition support)

Product Name: Mytesi	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of non-infectious diarrhea

AND

2 - Patient has evidence of concurrent HIV (human immunodeficiency virus) antiviral therapy

AND

3 - The requested daily dose does not exceed the maximum of 2 tablets per day

AND

4 - Patient is 18 years of age or older

Product Name: Relistor, Symproic	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 18 years of age or older

AND

2 - Patient has a history of chronic pain requiring continuous opioid therapy for 12 weeks or longer

AND

3 - One of the following

3.1 Patient has had an inadequate clinical response to a 14-day trial of THREE preferred* medications, including one which requires step therapy

OR

3.2 Patient has ONE of the following:

- Allergy to preferred medications
- Contraindication to or drug interaction to preferred medications
- History of unacceptable/toxic side effects to preferred medications

Notes	*NOTE: PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html

Product Name: Aemcolo	
Approval Length	3 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 18 years of age or older

AND

2 - Patient has a diagnosis of travelers' diarrhea

AND

3 - Inability to take, or failure of, at least one of the following:

- Azithromycin (generic Zithromax)
- Ciprofloxacin (generic Cipro)
- Levofloxacin (generic Levaquin)
- Ofloxacin (generic Floxin)
- Xifaxan (rifaximin)

2 . Revision History

Date	Notes
3/1/2022	New Guideline; re-classification of Gastrointestinal Agents

Prior Authorization Guideline

GL-100617 Gavreto

Formulary

Formulary Note

Guideline Note:

Effective Date:	2/1/2022

1 . Criteria

Product Name: Gavreto	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has a diagnosis of non-small cell lung cancer (NSCLC)	

AND

2 - The disease is ONE of the following

- Recurrent
- Advanced
- Metastatic

AND

3 - There is presence of RET gene fusion-positive or RET rearrangement positive tumors

Product Name: Gavreto	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following

1.1 All of the following

1.1.1 Patient has a diagnosis of ONE of the following

- Follicular carcinoma
- Hürthle cell carcinoma
- Papillary carcinoma

AND

1.1.2 ONE of the following

- Unresectable locoregional recurrent disease
- Persistent disease
- Metastatic disease

AND

1.1.3 Disease is RET-fusion positive

AND

1.1.4 Disease is not amenable to radioactive iodine therapy

OR

1.2 All of the following

1.2.1 Diagnosis of medullary carcinoma

AND

1.2.2 ONE of the following

- Disease is recurrent, persistent, or progressive
- Disease is symptomatic with distant metastases

AND

1.2.3 Disease is RET-mutation positive

OR

1.3 All of the following

1.3.1 Diagnosis of anaplastic carcinoma

AND

1.3.2 ONE of the following

- Disease is stage IVA or IVB (locoregional)
- Disease is metastatic

AND

1.3.3 Disease is RET-fusion positive

Product Name: Gavreto	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC), Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Gavreto therapy

Product Name: Gavreto	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Gavreto	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Documentation of positive clinical response to Gavreto therapy

2 . Revision History

Date	Notes
12/16/2021	Copy of NY

Prior Authorization Guideline

GL-104044 Genitourinary Agents, Urinary Antispasmodics

Formulary

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Brand Enablex, generic darifenacin ER, Brand Detrol, generic tolterodine, trospium, trospium ER, Brand Vesicare, Gemtesa, Brand Ditropan XL	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following*:

- Therapeutic failure to a 30 day trial of TWO preferred medications with different active ingredients
- Allergy to preferred medications

• Contraindication to, or drug interaction with, preferred medications • A history of unacceptable or toxic side effects to preferred medications	
Notes	*PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: brand Detrol LA, generic tolterodine ER	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 BOTH of the following:

- Patient is less than 18 years of age
- History of an inadequate clinical response to a 30 day trial of oxybutynin (IR or ER)

OR

1.2 Both of the following:

1.2.1 Patient is 18 years of age or older

AND

1.2.2 ONE of the following*:

- Therapeutic failure to a 30 day trial of TWO preferred medications with different active ingredients
- Allergy to preferred medications
- Contraindication to, or drug interaction with, preferred medications
- A history of unacceptable or toxic side effects to preferred medications

Notes	*PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Vesicare LS	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient is 2-5 years of age

OR

1.2 ONE of the following*:

- Therapeutic failure to a 30 day trial of TWO preferred medications with different active ingredients
- Allergy to preferred medications
- Contraindication to, or drug interaction with, preferred medications
- A history of unacceptable or toxic side effects to preferred medications

Notes	*PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Myrbetriq granules	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient is 3-5 years of age

OR

1.2 ONE of the following*:

• Therapeutic failure to a 30 day trial of TWO preferred medications with different active ingredients • Allergy to preferred medications • Contraindication to, or drug interaction with, preferred medications • A history of unacceptable or toxic side effects to preferred medications	
Notes	*PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
2/24/2022	Updated GL name to remove ":" Added Myrbetriq granules. Updated Vesicare LS criteria.

Prior Authorization Guideline

GL-77229 Genitourinary Agents: Benign Prostatic Hyperplasia

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2021

1 . Criteria

Product Name: Brand Cialis 2.5mg and 5mg, generic tadalafil 2.5mg and 5mg	
Diagnosis	Benign prostatic hyperplasia (BPH)
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of benign prostatic hyperplasia (BPH)	

AND **2** - Therapeutic failure to a 30 day trial of ONE alpha-1 adrenergic blocker **AND** **3** - Therapeutic failure to a 90 day trial of finasteride	
Notes	PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Brand Uroxatral, Cardura XL, Brand Rapaflo, generic silodosin, Brand Avodart, Brand Jalyn, generic dutasteride-tamsulosin	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Therapeutic failure to a 30 day trial of two preferred medications (*See Preferred Drug List) **OR** **2** - Patient has ONE of the following (*See Preferred Drug List): • An allergy to preferred medications • A contraindication to, or drug interaction with, preferred medications • A history of unacceptable or toxic side effects to preferred medications	
Notes	PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes

11/24/2020	Updated Cialis criteria. Removed generic alfuzosin and generic dutas teride

Prior Authorization Guideline

GL-77571 Genitourinary Agents: Electrolyte Depleter Agents

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2021

1 . Criteria

Product Name: Auryxia, Brand Fosrenol, generic lanthanum carbonate, Velphoro, Brand Renagel tablet, Brand Renvela tablet, Brand Renvela packet	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following (*See Preferred Drug List):

- An allergy to preferred medications
- A contraindication to, or drug interaction with, preferred medications

• A history of unacceptable or toxic side effects to preferred medications **OR** **2** - Patient has had an inadequate clinical response to a 7 day trial of two preferred medications (*See Preferred Drug List)	
Notes	*PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
11/30/2020	Generic sevelamer (generic for Renagel and Renvela) moved to preferred

Prior Authorization Guideline

GL-89262 Gilotrif

Formulary

Formulary Note

Guideline Note:

Effective Date:	9/1/2021

1 . Criteria

Product Name: Gilotrif	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of metastatic non-small cell lung cancer (NSCLC)	

AND

2 - ONE of the following:

- Squamous disease progressing after previous platinum-based chemotherapy
- Tumors are positive for non-resistant epidermal growth factor receptor (EGFR) mutations

Product Name: Gilotrif	
Diagnosis	Advanced Non-Nasopharyngeal Head and Neck Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced, non-nasopharyngeal head and neck cancer

AND

2 - Disease has progressed on or after platinum-containing chemotherapy

Product Name: Gilotrif	
Diagnosis	Brain Metastases
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of brain metastasis due to EGFR (epidermal growth factor receptor)-sensitizing mutation positive non-small cell lung cancer

Product Name: Gilotrif	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC), Advanced Non-Nasopharyngeal Head and Neck Cancer, Brain Metastases
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Gilotrif therapy

Product Name: Gilotrif	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Gilotrif will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Gilotrif	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Gilotrif therapy

2 . Revision History

Date	Notes
7/1/2021	Copied from NY. Updated brain metastases coverage based on NCCN guidelines.

Prior Authorization Guideline

GL-105450 Gleevec

Formulary

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Brand Gleevec, generic imatinib	
Diagnosis	Chronic myelogenous or myeloid leukemia (CML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chronic myelogenous or myeloid leukemia (CML)	

Product Name: Brand Gleevec, generic imatinib	
Diagnosis	Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL)

Product Name: Brand Gleevec, generic imatinib	
Diagnosis	Myelodysplastic Disease (MDS) or Myeloproliferative Disease (MPD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of myelodysplastic disease or myeloproliferative disease (MDS/MPD)

AND

2 - ONE of the following:

- Disease is associated with 5q32 (gene) translocations
- Disease is associated with platelet-derived growth factor receptor (PDGRF) beta gene re-arrangements
- Disease is associated with a t(5;12) translocation associated with the ETV6-PDGFR beta fusion gene

Product Name: Brand Gleevec, generic imatinib	
Diagnosis	Aggressive Systemic Mastocytosis (ASM)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of aggressive systemic mastocytosis (ASM)

AND

2 - ONE of the following:

- Patient is without the D816V c-Kit (gene)mutation
- c-Kit mutational status unknown
- Eosinophilia is present with FIP1L1-PDGFRA fusion gene

Product Name: Brand Gleevec, generic imatinib	
Diagnosis	Hypereosinophilic Syndrome (HES) / Chronic Eosinophilic Leukemia (CEL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of at least ONE of the following:

- Hypereosinophilic syndrome (HES)
- Chronic eosinophilic leukemia (CEL)

Product Name: Brand Gleevec, generic imatinib	
Diagnosis	Dermatofibrosarcoma Protuberans (DFSP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of dermatofibrosarcoma protuberans (DFSP)

Product Name: Brand Gleevec, generic imatinib	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Gastrointestinal stromal tumors (GIST)
- Desmoid tumors / aggressive fibromatosis
- Pigmented villonodular synovitis (PVNS) or tenosynovial giant cell tumor (TGCT)

Product Name: Brand Gleevec, generic imatinib	
Diagnosis	Chordoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chordoma

Product Name: Brand Gleevec, generic imatinib	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of melanoma

AND

2 - Patient has C-KIT (gene) mutation

Product Name: Brand Gleevec, generic imatinib	
Diagnosis	AIDS-Related Kaposi Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of AIDS (acquired immunodeficiency syndrome)-related Kaposi Sarcoma

AND

2 - Patient is currently being treated with antiretroviral therapy (ART)

AND

3 - Not used as first line therapy

Product Name: Brand Gleevec, generic imatinib	
Diagnosis	Steroid-Refractory Chronic Graft-Versus-Host Disease (GVHD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic graft-versus-host disease

AND

2 - Patient is currently being treated with systemic corticosteroids

AND

3 - Patient had no response to first-line therapy options

Product Name: Brand Gleevec, generic imatinib	
Diagnosis	Myeloid/Lymphoid Neoplasms with Eosinophilia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia

AND

2 - One of the following:

- FIP1L1-PDGFRA rearrangement
- PDGFRB rearrangement
- ABL1 rearrangement

Product Name: Brand Gleevec, generic imatinib	
Diagnosis	All Indications except NCCN

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Gleevec therapy

Product Name: Brand Gleevec, generic imatinib	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Product Name: Brand Gleevec, generic imatinib	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Gleevec therapy

2 . Revision History

Date	Notes
3/30/2022	Gleevec and imatinib GPI update.

Prior Authorization Guideline

GL-107876 Global Medical Necessity

Formulary

Formulary Note

Guideline Note:

Effective Date:	8/1/2022

1 . Criteria

Product Name: Non-Preferred Medications	
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - If the requested medication is a behavioral health medication, ONE of the following:

1.1 The patient has been receiving treatment with the requested non-preferred behavioral health medication and is new to the plan (enrollment effective date within the past 90 days

OR

1.2 The patient is currently receiving treatment with the requested non-preferred behavioral health medication in the hospital and must continue upon discharge

OR

2 - All of the following:

2.1 One of the following:

2.1.1 Both of the following:

2.1.1.1 One of the following:

- History of failure to at least three preferred alternatives as confirmed by claims history or submission of medical records.*
- History of contraindication or intolerance to three preferred alternatives (please specify contraindication or intolerance).*

AND

2.1.1.2 One of the following:

2.1.1.2.1 If the request is for a multi-source brand medication OR a branded medication with an authorized generic, ONE of the following:

- The brand is being requested because of an adverse reaction, allergy, or sensitivity to a generic/authorized generic equivalent (specify the adverse reaction, allergy, or sensitivity)
- The brand is being requested due to an incomplete response with a generic/authorized generic equivalent as documented by submission of medical records
- The brand is being requested because transition to a generic/authorized generic equivalent could result in destabilization of the patient
- Special clinical circumstances exist that preclude the use of a generic/authorized generic equivalent of the brand medication for the patient (document special clinical circumstances)

OR

2.1.1.2.2 If the request is for a generic when there is a brand available and the brand is the preferred formulation, ONE of the following:

- The generic is being requested because of an adverse reaction, allergy, or sensitivity to the brand (specify the adverse reaction, allergy, or sensitivity)
- The generic is being requested due to an incomplete response with the brand, as documented by submission of medical records
- The generic is being requested because transition to the brand could result in destabilization of the patient.
- Special clinical circumstances exist that preclude the use of the brand equivalent of the generic medication for the patient (document special clinical circumstances)

OR

2.1.2 There are no preferred formulary alternatives for the requested drug.

AND

2.2 One of the following:

2.2.1 The requested drug must be used for a Food and Drug Administration (FDA)-approved indication

OR

2.2.2 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopeia-National Formulary (USP-NF)

AND

2.3 The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plan’s program

Notes	* Prior trials of formulary/PDL alternatives must sufficiently demonstrate that the formulary/PDL alternatives are either ineffective or inappropriate at the time of the request. NOTE: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication or intolerance to ALL the preferred products. PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html

Product Name: Preferred with Prior Authorization Medications (for medications that lack drug specific criteria)	
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - ONE of the following:

1.1 The requested drug must be used for an FDA-approved indication

OR

1.2 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopeia-National Formulary (USP-NF)

AND

2 - The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plan's program

Notes	OH PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html

2 . Revision History

Date	Notes
6/9/2022	Updated failure, contraindication, and intolerance language within the policy. Updated the brand/generic language to include submission of medical records and/or documentation where necessary.

Prior Authorization Guideline

GL-101694 Global Quantity Limits

Formulary

Formulary Note

Guideline Note:

Effective Date:	9/10/2021

1 . Criteria

Product Name: Quantity Limit, Prescription Limit	
Diagnosis	Quantity limit review (General)
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - ONE of the following:

1.1 The requested drug must be used for an FDA-approved indication

OR

1.2 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

AND

2 - The drug is being prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in ONE of the following compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

AND

3 - The requested dosage cannot be achieved using the plan accepted quantity limit of a different dose or formulation.

AND

4 - The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program.

Product Name: Quantity Limit, Prescription Limit	
Diagnosis	Quantity limit review for the treatment of gender dysphoria*
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

AND

2 - The drug is being prescribed for an indication that is recognized as a covered benefit by the applicable health plans' program.

Notes	* If the above criteria are not met, then refer for clinical review by an a ppropriate trained professional (physician or pharmacist) based on the applicable regulatory requirement.

Product Name: Quantity Limit, Prescription Limit	
Diagnosis	Monthly prescription limit review for migraine therapy, benzodiazepines, opioids, or muscle relaxants
Approval Length	1 month(s)
Guideline Type	Administrative

Approval Criteria

1 - Medical necessity rationale provided for why the member requires 5 or more fills of the same drug or drug class within a month.

Notes	*If deemed medically necessary, longer authorization duration is perm itted

Product Name: Quantity Limit, Prescription Limit	
Diagnosis	Topical products exceeding the allowable package size per fill OR the allowable quantity per month
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - The physician attests that a larger quantity is needed for treatment of a larger surface area.

2 . Revision History

Date	Notes
1/10/2022	Corrected criteria

Prior Authorization Guideline

GL-96540 Grastek, Ragwitek

Formulary

Formulary Note

Guideline Note:

Effective Date:	12/1/2021

1 . Criteria

Product Name: Grastek	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe grass pollen-induced allergic rhinitis defined by symptoms severe enough to interfere with quality of life (e.g., sleep disturbances; impairment of daily, sport, or leisure activities; impairment of school or work performance)

AND

2 - Diagnosis confirmed by one of the following:

- Positive skin test to Timothy grass or cross-reactive grass pollens (e.g., Sweet Vernal, Orchard/Cocksfoot, Perennial Rye, Kentucky blue/June grass, Meadow Fescue, or Redtop)
- In vitro testing for pollen-specific IgE (immunoglobulin E) antibodies for Timothy grass or cross-reactive grass pollens (e.g., Sweet Vernal, Orchard/Cocksfoot, Perennial Rye, Kentucky blue/June grass, Meadow Fescue, or Redtop)

AND

3 - Treatment is started or will be started at least 12 weeks before the beginning of the grass pollen season

AND

4 - History of failure, contraindication, or intolerance to two of the following:

- oral antihistamine [e.g., cetirizine (Zyrtec)]
- intranasal antihistamine [e.g., azelastine (Astelin)]
- intranasal corticosteroid [e.g., fluticasone (Flonase)]
- leukotriene inhibitor [e.g., montelukast (Singulair)]

AND

5 - Not received in combination with similar cross-reactive grass pollen immunotherapy (e.g., Oralair)

AND

6 - Patient does not have unstable and/or uncontrolled asthma

AND

7 - Prescribed by or in consultation with a specialist in allergy and immunology

Product Name: Grastek	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Grastek therapy

Product Name: Ragwitek	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe short ragweed pollen-induced allergic rhinitis defined by symptoms severe enough to interfere with quality of life (e.g., sleep disturbances; impairment of daily, sport, or leisure activities; impairment of school or work performance)

AND

2 - Diagnosis confirmed by one of the following:

- Positive skin test to short ragweed pollen
- In vitro testing for pollen-specific IgE (immunoglobulin E) antibodies for short ragweed pollen

AND

3 - Treatment is started or will be started at least 12 weeks before the beginning of the short ragweed pollen season

AND

4 - History of failure, contraindication, or intolerance to two of the following:

- oral antihistamine [e.g., cetirizine (Zyrtec)]
- intranasal antihistamine [e.g., azelastine (Astelin)]
- intranasal corticosteroid [e.g., fluticasone (Flonase)]
- leukotriene inhibitor [e.g., montelukast (Singulair)]

AND

5 - Patient does not have unstable and/or uncontrolled asthma

AND

6 - Prescribed by or in consultation with a specialist in allergy and immunology

Product Name: Ragwitek	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Ragwitek therapy

Prior Authorization Guideline

GL-72468 HCG

Formulary

Formulary Note

Guideline Note:

Effective Date:	11/1/2020

1 . Criteria

Product Name: Novarel, Ovidrel, Brand Pregnyl, generic chorionic gonadotropin	
Diagnosis	Prepubertal Cryptorchidism
Approval Length	6 Week(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of prepubertal cryptorchidism not due to anatomical obstruction	

2 . Revision History

Date	Notes
9/1/2020	Added Novarel GPI

Prior Authorization Guideline

GL-88527 Hetlioz

Formulary

Formulary Note

Guideline Note:

Effective Date:	8/1/2021

1 . Criteria

Product Name: Hetlioz, Hetlioz LQ	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of non-24-hour sleep wake disorder (also known as free-running disorder,

free-running or non-entrained type circadian rhythm sleep disorder, or hypernychthemeral syndrome)

AND

1.1.2 Patient is totally blind (has no light perception)

OR

1.2 Diagnosis of nighttime sleep disturbances in Smith-Magenis-Syndrome (SMS)

AND

2 - ONE of the following:

2.1 History of contraindication or intolerance to melatonin therapy

OR

2.2 BOTH of the following:

2.2.1 History of failure of at least 6 months of continuous therapy (i.e., uninterrupted daily treatment) with melatonin

AND

2.2.2 Continuous trial of melatonin was done under the guidance of a specialist in sleep disorders

AND

3 - Prescribed by or in consultation with a specialist in sleep disorders

Product Name: Hetlioz, Hetlioz LQ	
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Prior Authorization Guideline

GL-81339 Horizant

Formulary

Formulary Note

Guideline Note:

Effective Date:	4/1/2021

1 . Criteria

Product Name: Horizant	
Diagnosis	Neuropathic Pain*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following

1.1 Patient has had a therapeutic failure to a 30-day trial of TWO preferred medications in separate pharmacologic classes

OR

1.2 Patient has allergy to preferred medications

OR

1.3 Patient has a contraindication to or drug interaction with preferred medications

OR

1.4 Patient has a history of unacceptable/toxic side effects to preferred medications authorization

Notes	*Applies to Central Nervous System (CNS) Agents: Neuropathic Pain. PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html

Product Name: Horizant	
Diagnosis	Restless Legs Syndrome*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient has had a therapeutic failure to a 30-day trial of ONE preferred medication

OR

1.2 Patient has allergy to preferred medications

OR

1.3 Patient has a contraindication to or drug interaction with preferred medications **OR** **1.4** Patient has a history of unacceptable/toxic side effects to preferred medications	
Notes	*Applies to Central Nervous System (CNS) Agents: Restless Legs Syndrome PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html

2 . Revision History

Date	Notes
2/19/2021	Updated criteria and notes

Prior Authorization Guideline

GL-100507 Hycamtin

Formulary

Formulary Note

Guideline Note:

Effective Date:	2/1/2022

1 . Criteria

Product Name: Brand Hycamtin, generic topotecan	
Diagnosis	Small Cell Lung Cancer (SCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of small cell lung cancer (SCLC)	

AND

2 - Patient has experienced a relapse of disease after initial first-line chemotherapy (e.g., cisplatin with etoposide)

Product Name: Brand Hycamtin, generic topotecan	
Diagnosis	Merkel Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Merkel cell carcinoma

AND

2 - BOTH of the following:

- Disseminated disease
- Clinical M1 disease

AND

3 - Patient has a contraindication to checkpoint immunotherapy [e.g., Bavencio (avelumab), Keytruda (pembrolizumab), Opdivo (nivolumab)]

Product Name: Brand Hycamtin, generic topotecan	
Diagnosis	Endometrial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of endometrial carcinoma

AND

2 - Used as adjuvant treatment for uterine-confined disease

AND

3 - Disease is recurrent, metastatic, or high-risk

Product Name: Brand Hycamtin, generic topotecan	
Diagnosis	Small Cell Lung Cancer (SCLC), Merkel Cell Carcinoma, Endometrial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Hycamtin (topotecan) therapy

Product Name: Brand Hycamtin, generic topotecan	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Brand Hycamtin, generic topotecan	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Hycamtin (topotecan) therapy

Prior Authorization Guideline

GL-66625 Ibrance

Formulary

Formulary Note

Guideline Note:

Effective Date:	8/1/2020

1 . Criteria

Product Name: Ibrance	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced, recurrent, or metastatic breast cancer

AND

2 - Disease is hormone-receptor (HR)-positive

AND

3 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

4 - ONE of the following:

- Used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane)
- Used in combination with Faslodex (fulvestrant)

Product Name: Ibrance	
Diagnosis	Well-Differentiated/Dedifferentiated Liposarcoma (WD-DDLS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of unresectable well-differentiated/dedifferentiated liposarcoma (WD-DDLS)

Product Name: Ibrance	
Diagnosis	Breast Cancer, Well-Differentiated/Dedifferentiated Liposarcoma (WD-DDLS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Ibrance therapy

Product Name: Ibrance	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Ibrance will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Ibrance	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Ibrance therapy

2 . Revision History

Date	Notes
5/20/2020	Updated coverage criteria for WD-DDLS per NCCN recommendations

Prior Authorization Guideline

GL-99835 Iclusig

Formulary

Formulary Note

Guideline Note:

Effective Date:	2/1/2022

1 . Criteria

Product Name: Iclusig	
Diagnosis	Chronic Myelogenous / Myeloid Leukemia (CML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chronic myelogenous/ myeloid leukemia (CML)	

AND

2 - ONE of the following:

2.1 BOTH of the following:

- Disease is in the chronic phase
- Patient is unable to take or has failed treatment with TWO or more tyrosine kinase inhibitor (TKI) therapies [e.g., imatinib mesylate, Sprycel (dasatinib), or Tasigna (nilotinib)]

OR

2.2 Confirmed documentation of T315I mutation

OR

2.3 BOTH of the following:

- Disease is in the accelerated or blast phase
- No other kinase inhibitors are indicated

Product Name: Iclusig	
Diagnosis	Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia (Ph+ALL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ALL)

AND

2 - ONE of the following:

2.1 No other kinase inhibitors are indicated

OR

2.2 Confirmed documentation of T315I mutation

OR

2.3 Used as a component of Hyper-CVAD (chemotherapy) regimen induction or consolidation

Product Name: Iclusig	
Diagnosis	Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia

AND

2 - ONE of the following:

2.1 Patient has FGFR1 (fibroblast growth factor receptor 1) rearrangement

OR

2.2 Patient has ABL1 (gene) rearrangement

Product Name: Iclusig

Diagnosis	Chronic Myelogenous / Myeloid Leukemia (CML), Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia (Ph+ALL), Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Iclusig therapy

Product Name: Iclusig	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Iclusig will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Iclusig	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Iclusig therapy

2 . Revision History

Date	Notes
12/8/2021	Updated GPI's. Updated Ph+ALL and CML criteria to reflect package insert and NCCN recommendations.

Prior Authorization Guideline

GL-56541 Idhifa

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2020
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Idhifa	
Diagnosis	Acute Myeloid Leukemia (AML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - AML is IDH2 (isocitrate dehydrogenase 2) mutation-positive

AND

3 - ONE of the following:

3.1 Disease is relapsed or refractory

OR

3.2 BOTH of the following:

3.2.1 Patient is 60 years of age or older

AND

3.2.2 ONE of the following:

- Patient is not a candidate for intensive induction therapy
- Used for post remission therapy following response to low intensity induction therapy

Product Name: Idhifa	
Diagnosis	Acute Myeloid Leukemia (AML)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Idhifa therapy

Product Name: Idhifa	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Idhifa will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Idhifa	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Idhifa therapy

2 . Revision History

Date	Notes
11/6/2019	New Guideline.

Prior Authorization Guideline

GL-78347 Ilaris

Formulary

Formulary Note

Guideline Note:

Effective Date:	2/1/2021

1 . Criteria

Product Name: Ilaris	
Diagnosis	Cryopyrin-Associated Periodic Syndromes (CAPS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Familial cold autoinflammatory syndrome (FCAS)

- Muckle-Wells Syndrome (MWS)

AND

2 - Diagnosis is made by, or in consultation with, a rheumatologist or immunologist with expertise in the diagnosis of FCAS and MWS

Product Name: Ilaris	
Diagnosis	Cryopyrin-Associated Periodic Syndromes (CAPS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is currently on Ilaris therapy for ONE of the following:

- Familial cold autoinflammatory syndrome (FCAS)
- Muckle-Wells Syndrome (MWS)

AND

2 - Documentation of positive clinical response to Ilaris therapy

Product Name: Ilaris	
Diagnosis	Tumor Necrosis Factor (TNF) Receptor-Associated Periodic Syndrome (TRAPS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of tumor necrosis factor (TNF) receptor-associated periodic syndrome (TRAPS)

AND

2 - Diagnosis is made by, or in consultation with, a rheumatologist or immunologist with expertise in the diagnosis of TRAPS

Product Name: Ilaris	
Diagnosis	Tumor Necrosis Factor (TNF) Receptor-Associated Periodic Syndrome (TRAPS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is currently on Ilaris therapy for tumor necrosis factor (TNF) receptor-associated periodic syndrome (TRAPS)

AND

2 - Documentation of positive clinical response to Ilaris therapy, defined as a decrease in frequency or severity of attacks

Product Name: Ilaris	
Diagnosis	Hyperimmunoglobulin D (Hyper-IgD) Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following

- Hyperimmunoglobulin D (Hyper-IgD) Syndrome (HIDS)

- Mevalonate Kinase Deficiency (MKD)

AND

2 - Diagnosis is made by, or in consultation with, a rheumatologist or immunologist with expertise in the diagnosis of HIDS or MKD

Product Name: Ilaris	
Diagnosis	Hyperimmunoglobulin D (Hyper-IgD) Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is currently on Ilaris therapy for ONE of the following:

- Hyperimmunoglobulin D (Hyper-IgD) Syndrome (HIDS)
- Mevalonate Kinase Deficiency (MKD)

AND

2 - Documentation of positive clinical response to Ilaris therapy, defined as a decrease in frequency or severity of attacks

Product Name: Ilaris	
Diagnosis	Familial Mediterranean Fever (FMF)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Familial Mediterranean Fever (FMF)

AND

2 - Diagnosis is made by, or in consultation with, a rheumatologist or immunologist with expertise in the diagnosis of FMF

AND

3 - History of failure, contraindication, or intolerance to colchicine

Product Name: Ilaris	
Diagnosis	Familial Mediterranean Fever (FMF)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is currently on Ilaris therapy for Familial Mediterranean Fever (FMF)

AND

2 - Documentation of positive clinical response to Ilaris therapy, defined by a decrease in index disease flare or normalization of CRP (C-reactive protein)

Product Name: Ilaris	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of systemic juvenile idiopathic arthritis (SJIA)

AND

2 - Diagnosis is made by, or in consultation with, a rheumatologist or immunologist with expertise in the diagnosis of SJIA

AND

3 - Patient is not receiving Ilaris in combination with another biologic (e.g., Actemra)

Product Name: Ilaris	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is currently on Ilaris therapy for systemic juvenile idiopathic arthritis (SJIA)

AND

2 - Documentation of positive clinical response to Ilaris therapy

AND

3 - Patient is not receiving Ilaris in combination with another biologic (e.g., Actemra)

Product Name: Ilaris	
Diagnosis	Still’s Disease [Adult-Onset Still’s Disease (AOSD)]
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Adult Onset Still's Disease (AOSD)

AND

2 - Diagnosis is made by, or in consultation with, a rheumatologist or immunologist with expertise in the diagnosis of Still's Disease

AND

3 - Patient is not receiving Ilaris in combination with another biologic (e.g., Actemra)

Product Name: Ilaris	
Diagnosis	Still's Disease [Adult-Onset Still's Disease (AOSD)]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is currently on Ilaris therapy for Adult Onset Still's Disease (AOSD)

AND

2 - Documentation of positive clinical response to Ilaris therapy

AND

3 - Patient is not receiving Ilaris in combination with another biologic (e.g., Actemra)

Prior Authorization Guideline

GL-96964 Imbruvica

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: Imbruvica	
Diagnosis	B-Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

1.1.1 Diagnosis of mantle cell lymphoma (MCL)

AND

1.1.2 ONE of the following:

- Patient has received at least one prior therapy for MCL
- Used in pre-treatment therapy in combination with Rituxan (rituximab) to limit the number of cycles with RHyperCVAD (cyclophosphamide, vincristine, doxorubicin, and dexamethasone) regimen

OR

1.2 Diagnosis of ONE of the following:

- Chronic Lymphocytic Leukemia (CLL)
- Small Lymphocytic Lymphoma (SLL)

OR

1.3 BOTH of the following:

1.3.1 Diagnosis of ONE of the following:

- Follicular lymphoma (grade 1-2)
- Diffuse large B-cell lymphoma [non-GCB DLBCL (non-germinal center B-cell diffuse large B-cell) and non-candidate for transplant]
- Acquired immune deficiency syndrome (AIDS)-related B-cell lymphoma
- Post-transplant lymphoproliferative disorders
- Histologic transformation to diffuse large B-cell lymphoma
- Hairy cell leukemia
- Nodal or splenic marginal zone lymphoma (MZL)
- Gastric MALT (mucosa-associated lymphoid tissue) lymphoma
- Nongastric MALT lymphoma
- High grade B-cell lymphoma

AND

1.3.2 Used as second-line or a subsequent therapy

Product Name: Imbruvica	
Diagnosis	Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma

Product Name: Imbruvica	
Diagnosis	Primary CNS Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary central nervous system (CNS) lymphoma

AND

2 - ONE of the following:

2.1 Used as second-line or a subsequent therapy

OR

2.2 Used as induction therapy if the patient is unsuitable or intolerant to high-dose methotrexate

Product Name: Imbruvica	
Diagnosis	B-Cell Lymphoma, Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma, Primary CNS Lymphoma

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Imbruvica therapy

Product Name: Imbruvica	
Diagnosis	Chronic Graft Versus Host Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic graft versus host disease

AND

2 - History of failure of at least one other systemic therapy [e.g. corticosteroids, mycophenolate, etc.]

Product Name: Imbruvica	
Diagnosis	Chronic Graft Versus Host Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient shows evidence of positive clinical response while on Imbruvica therapy

Product Name: Imbruvica	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Imbruvica will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Imbruvica	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Imbruvica therapy

2 . Revision History

Date	Notes
10/19/2021	Update

Prior Authorization Guideline

GL-99087 Immunomodulator Agents for Systemic Inflammatory Disease

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: Humira, Simponi, Xeljanz IR	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	56 Day(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a diagnosis of moderate to severe ulcerative colitis (UC)

AND

2 - The patient has a prior history of first-generation therapy appropriate for the diagnosis

AND

3 - The patient has no current infection

AND

4 - ONE of the following:

4.1 If the request is for Humira, the patient had an inadequate clinical response to 90 days of therapy with BOTH of the following:

- 5-ASA (aminosalicylic acids)
- Immunosuppressants

OR

4.2 If the request is for Simponi or Xeljanz IR, ONE of the following:

4.2.1 The patient had an initial clinical response to Humira after 56 days of therapy but no improvement in the progression of ulcerative colitis symptoms after 180 days*

OR

4.2.2 ONE of the following**:

- Patient has an allergy to preferred medications
- Patient has a contraindication to, or drug interaction with, preferred medications
- Patient has a history of unacceptable/toxic side effects to preferred medications

AND

5 - The request does not exceed ONE of the following quantity limits:

- For Humira: 7 pens/syringes during the first 30 days, then 2 pens/syringes per 30 days
- For Simponi: 3 pens/syringes during the first 30 days, then 1 pen/syringe per 30 days
- For Xeljanz: 60 pills per 30 days

Notes	*If clinical response is not seen in 56 days, further therapy with TNF inhibitors will not be approved **PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Humira, Simponi, Xeljanz IR	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a diagnosis of moderate to severe ulcerative colitis (UC)

AND

2 - The patient has no current infection

AND

3 - Patient had a clinical response to the requested medication

AND

4 - The request does not exceed ONE of the following quantity limits:

- For Humira: 2 pens/syringes per 30 days
- For Simponi: 1 pen/syringe per 30 days
- For Xeljanz: 60 pills per 30 days

Product Name: Humira, Enbrel, Kineret, Otezla, Xeljanz IR	
Diagnosis	All Diagnoses Except Ulcerative Colitis
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a diagnosis of ONE of the following:

- Rheumatoid Arthritis
- Plaque Psoriasis
- Psoriatic Arthritis
- Polyarticular Juvenile Idiopathic Arthritis
- Crohn's Disease
- Ankylosing Spondylitis
- Psoriasis
- Uveitis
- Cryopyrin-Associated Periodic Syndrome
- Giant Cell Arteritis
- Hidradenitis Suppurativa

AND

2 - The patient has a prior history of first-generation therapy appropriate for the diagnosis

AND

3 - The patient has no current infection

AND

4 - If the request is for Humira or Enbrel for moderate to severe plaque psoriasis, the patient has had an inadequate response to 90 days of phototherapy

Product Name: Simponi	
Diagnosis	Non-Preferred (All Diagnoses Except Ulcerative Colitis)
Approval Length	12 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a diagnosis of ONE of the following:

- Rheumatoid Arthritis
- Plaque Psoriasis
- Psoriatic Arthritis
- Polyarticular Juvenile Idiopathic Arthritis
- Crohn's Disease
- Ankylosing Spondylitis
- Psoriasis
- Uveitis
- Cryopyrin-Associated Periodic Syndrome
- Giant Cell Arteritis
- Hidradenitis Suppurativa

AND

2 - The patient has a prior history of first-generation therapy appropriate for the diagnosis

AND

3 - The patient has no current infection

AND

4 - ONE of the following:

4.1 Patient has had a therapeutic failure to a 90 day trial of TWO preferred medications*

OR

4.2 ONE of the following:

- Patient has an allergy to preferred medications
- Patient has a contraindication to, or drug interaction with, preferred medications

• Patient has a history of unacceptable/toxic side effects to preferred medications	
Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Taltz	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a diagnosis of ONE of the following:

- Rheumatoid Arthritis
- Plaque Psoriasis
- Psoriatic Arthritis
- Polyarticular Juvenile Idiopathic Arthritis
- Crohn's Disease
- Ankylosing Spondylitis
- Psoriasis
- Uveitis
- Cryopyrin-Associated Periodic Syndrome
- Giant Cell Arteritis
- Hidradenitis Suppurativa

AND

2 - The patient has a prior history of first-generation therapy appropriate for the diagnosis

AND

3 - The patient has no current infection

AND

4 - Patient has had an inadequate clinical response to a 30-day trial of ONE preferred TNF (tumor necrosis factor) inhibitor

Product Name: Cimzia, Orencia, Actemra, Ilumya, Kevzara, Siliq, Skyrizi, Tremfya, Olumiant, Xeljanz XR, Xeljanz Soln, Rinvoq, Cosentyx, Stelara	
Diagnosis	Non-Preferred
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a diagnosis of ONE of the following:

- Rheumatoid Arthritis
- Plaque Psoriasis
- Psoriatic Arthritis
- Polyarticular Juvenile Idiopathic Arthritis
- Crohn's Disease
- Ankylosing Spondylitis
- Psoriasis
- Uveitis
- Cryopyrin-Associated Periodic Syndrome
- Giant Cell Arteritis
- Hidradenitis Suppurativa

AND

2 - The patient has a prior history of first-generation therapy appropriate for the diagnosis

AND

3 - The patient has no current infection

AND

4 - ONE of the following:

4.1 Patient has had a therapeutic failure to a 90-day trial of TWO preferred medications*

OR

4.2 ONE of the following: • Patient has an allergy to preferred medications • Patient has a contraindication to, or drug interaction with, preferred medications • Patient has a history of unacceptable/toxic side effects to preferred medications

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
12/1/2021	Updated GPI Table. Combined sections to simplify. Kineret, Otezla, and Xeljanz 10 mg preferred now. Taltz step therapy now.

Prior Authorization Guideline

GL-57024 Increlex

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2020

1 . Criteria

Product Name: Increlex	
Diagnosis	Severe Primary IGF-1 Deficiency / Growth Hormone Gene Deletion
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Documentation of ALL of the following:

1.1.1 Diagnosis of severe primary IGF-1 (insulin-like growth factor-1) deficiency

AND

1.1.2 Height standard deviation score less than or equal to -3.0

AND

1.1.3 Basal IGF-1 standard deviation score less than or equal to -3.0

AND

1.1.4 Normal or elevated growth hormone levels

AND

1.1.5 Documentation of open epiphyses on last bone radiograph

AND

1.1.6 The patient will not be treated with concurrent growth hormone therapy

AND

1.1.7 Prescribed by an endocrinologist

OR

1.2 ALL of the following:

1.2.1 Diagnosis of growth hormone gene deletion and has developed neutralizing antibodies to growth hormone

AND

1.2.2 Documentation of open epiphyses on last bone radiograph

AND

1.2.3 The patient will not be treated with concurrent growth hormone therapy

AND

1.2.4 Prescribed by an endocrinologist

Product Name: Increlex	
Diagnosis	Severe Primary IGF-1 Deficiency / Growth Hormone Gene Deletion
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 cm (centimeters) per year over the previous year of treatment as documented by BOTH of the following:

1.1 Previous height and date obtained

AND

1.2 Current height and date obtained

AND

2 - Documentation of BOTH of the following:

2.1 Expected adult height not obtained

AND

2.2 Expected adult height goal

AND

3 - Patient is not treated with concurrent growth hormone therapy

AND

4 - Prescribed by an endocrinologist

2 . Revision History

Date	Notes
11/18/2019	C&S Implementation

Prior Authorization Guideline

GL-99080 Infectious Disease Agents Antibiotics - Macrolides

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: E.E.S., brand Eryped, brand Ery-tab, brand Erythrocin, generic erythromycin	
Approval Length	30 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - If the request is for a non-preferred medication*, ONE of the following:

1.1 Patient has had a therapeutic failure to a THREE day trial of ONE preferred medication*

OR

1.2 Patient cannot be changed to a preferred medication due to ONE of the following:

- Patient has an allergy to preferred medications
- Patient has a contraindication to, or drug interaction with, preferred medications
- Patient has a history of unacceptable/toxic side effects to preferred medications

OR

1.3 The infection is caused by an organism resistant to preferred medications **

OR

1.4 The requested medication was initiated in the hospital and the request is to complete the course of therapy

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP ** Include the diagnosis and any culture and sensitivity reports

2 . Revision History

Date	Notes
12/1/2021	Updated GPI's and NP language

Prior Authorization Guideline

GL-57092 Infectious Disease Agents Antibiotics – Cephalosporins

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2020

1 . Criteria

Product Name: Brand Keflex 750 mg, generic cephalexin 750 mg, generic cefaclor suspension, generic cefprozil suspension, generic cefpodoxime tablets and suspension, Brand Suprax suspension, capsules and chew tablets, generic cefixime suspension and capsules*	
Approval Length	30 Day(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has had a therapeutic failure to a THREE day trial of ONE preferred medication **	

OR

2 - Patient cannot be changed to a preferred medication due to ONE of the following

2.1 Patient has an allergy to preferred medications

OR

2.2 Patient has a contraindication to, or drug interaction with, preferred medications

OR

2.3 Patient has a history of unacceptable/toxic side effects to preferred medications

OR

3 - The infection is caused by an organism resistant to preferred medications ***

OR

4 - The requested medication was initiated in the hospital and the request is to complete the course of therapy

Notes	*Prior authorization is required for age over 12 for the following medications: generic cefaclor suspension, generic cefprozil suspension ** PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP *** Include the diagnosis and any culture and sensitivity reports

2 . Revision History

Date	Notes
11/21/2019	C&S Implementation

Prior Authorization Guideline

GL-99038 Infectious Disease Agents, Antibiotics - Inhaled

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: Bethkis, Tobi Podhaler, Brand Tobi, Kitabis Pak, generic tobramycin inhalation soln	
Approval Length	28 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of cystic fibrosis with pseudomonas-related infection

AND

2 - Patient is 6 years of age or older

AND

3 - Is prescribed in “Pulse” dosing cycles of 28 days on drug, followed by 28 days off drug

AND

4 - If the request is for a non-preferred medication*, ONE of the following:

4.1 Patient cannot be changed to a preferred medication due to ONE of the following: *

4.1.1 Patient has an allergy to preferred medications

OR

4.1.2 Patient has a contraindication to or drug interaction with preferred medications

OR

4.1.3 Patient has a history of unacceptable/toxic side effects to preferred medications

OR

4.2 Patient has had a 28 day trial of ONE preferred medication *

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Cayston	
Approval Length	28 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of cystic fibrosis with pseudomonas-related infection

AND

2 - Patient is 7 years of age or older

AND

3 - Is prescribed in “Pulse” dosing cycles of 28 days on drug, followed by 28 days off drug

AND

4 - If the request is for a non-preferred medication*, ONE of the following:

4.1 Patient cannot be changed to a preferred medication due to ONE of the following: *

4.1.1 Patient has an allergy to preferred medications

OR

4.1.2 Patient has a contraindication to or drug interaction with preferred medications

OR

4.1.3 Patient has a history of unacceptable/toxic side effects to preferred medications

OR

4.2 Patient has had a 28 day trial of ONE preferred medication *

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Brand Arikayce

Diagnosis	Mycobacterium avium complex (MAC)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of Mycobacterium avium complex (MAC) lung disease

AND

2 - Patient has not achieved negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy (e.g. macrolide, rifampin, & ethambutol)

AND

3 - Dose will be limited to 1 dose per day

Product Name: Brand Arikayce	
Diagnosis	Mycobacterium avium complex (MAC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Evidence of culture conversion (negative sputum culture)

AND

2 - Dose is limited to 1 dose per day

2 . Revision History

Date	Notes
12/1/2021	Consolidated tobramycin sections. Added generic Bethkis. Updated Cayston NP language.

Prior Authorization Guideline

GL-99009 Infectious Disease Agents, Antivirals - Hepatitis C Agents

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: Pegasys	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is approved for a DAA (direct-acting antiviral) regimen containing the requested medication

AND

2 - Patient should be monitored closely with periodic clinical and laboratory evaluations

Product Name: ribavirin caps/tabs	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is approved for a DAA (direct-acting antiviral) regimen containing the requested medication

AND

2 - BOTH of the following:

2.1 Patient is NOT pregnant, nor is planning to become pregnant during treatment or within 6 months of stopping

AND

2.2 Patient is NOT a male with a pregnant female partner

AND

3 - Agreement that partners will use two forms of contraception during treatment and for at least 6 months after stopping

AND

4 - Verification that monthly pregnancy tests will be performed throughout treatment

Product Name: Brand Epclusa, generic sofosbuvir/velpatasvir, Mavyret, Brand Harvoni, generic ledipasvir/sofosbuvir, Sovaldi, Vosevi, Zepatier, Viekira Pak	
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory tests/values, assessments) of ALL of the following:

1.1 Patient has an active HCV (Hepatitis C virus) infection verified by viral load within 180 days (document HCV RNA value and date)

AND

1.2 Patient's HCV genotype verified by lab (document genotype)

AND

1.3 Documentation of Hepatitis fibrosis stage, date, and method(s) used

AND

1.4 If patient is to receive an HCVNS3 protease inhibitor (i.e., grazoprevir, voxilaprevir, glecaprevir), and cirrhosis is determined to be likely present [as evidenced by clinical findings, radiology, Metavir fibrosis score of F4, pathology findings, or other laboratory markers (FibroTest/FibroSure/FIB-4 index)], the patient must be assessed for a history of decompensated liver disease and liver disease severity using the Child-Turcotte-Pugh (CTP) score

AND

1.5 Prescriber has discussed the importance of adherence to treatment plan, office visits, lab monitoring, imaging, procedures, and to taking requested regimen as prescribed

AND

1.6 Patient does NOT have limited life expectancy (less than 12 months) due to non-liver-related comorbid conditions

AND

1.7 If the patient is treatment-experienced, documentation of BOTH of the following, if applicable:

1.7.1 Prior treatment regimens, dates and outcomes, including reason for failure, if known (e.g., failed to complete prior therapy, failure of past therapy)

AND

1.7.2 If reason for prior failure is non-adherence to prior therapy or failure to complete therapy, documentation of what is different this time to try to improve the outcome

AND

2 - ONE of the following:

2.1 The requested regimen is an approvable regimen based on patient genotype and characteristics listed in the Background

OR

2.2 If the patient is 18 years old or over, the requested regimen is in accordance with AASLD/IDSA (American Association for the Study of Liver Diseases/Infectious Diseases Society of America) guidelines

OR

2.3 If the patient is under the age of 18 years old, the requested regimen is an FDA (Food and Drug Administration)-approved pediatric formulation of DAA and used in accordance with current AASLD guidelines

AND

3 - If the request is non-preferred*, the patient cannot be changed to a preferred* medication within the same class due to ONE of the following:

• Allergy to preferred medications • Contraindication to or drug interaction with preferred medications • History of unacceptable/toxic side effects to preferred medications • Patient is established on current therapy with prior payer (i.e., Commercial, Fee-for-Service, Managed Care Plan, etc.)	
Notes	Approval length is by regimen based on patient genotype and characteristics listed in Background. Please reference the AASLD/IDSA guidelines for those 18 years old and over. FDA-approved pediatric formulations of DAAs will be approved for those under the age of 18 years when used in accordance with current AASLD guidelines. AASLD: https://www.hcvguidelines.org/contents *PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Background

Benefit/Coverage/Program Information

Table 1. Approvable regimens

Treatment naïve
No cirrhosis ❑ Mavyret 100/40 mg, three (3) tablets daily for 8 weeks (for GT5/6 and/or HIV/HCV co-infection, 12 weeks is recommended) ❑ sofosbuvir/velpatasvir 400/100 mg, one tablet daily for 12 weeks
Compensated cirrhosis, HIV negative ❑ Mavyret 100/40 mg, three (3) tablets daily for 8 weeks ❑ sofosbuvir/velpatasvir 400/100, one tablet daily for 12 weeks (for GT3, add weight based RBV if Y93H positive)
Compensated cirrhosis, HIV positive ❑ Mavyret 100/40 mg, three (3) tablets daily for 12 weeks

❑ sofosbuvir/velpatasvir 400/100 mg, one tablet daily for 12 weeks (for GT3, add weight based RBV if Y93H positive)

Treatment experienced

Sofosbuvir-based regimen

❑ Mavyret 100/40 mg, three (3) tablets daily for 16 weeks

NS3/4 protease inhibitor inclusive regimen (e.g. Zepatier)

❑ Vosevi 400/100/100 mg, one tablet daily for 12 weeks

Mavyret

❑ Vosevi 400/100/100 mg, one tablet daily for 12 weeks (if compensated cirrhosis, add weight-based RBV)

Vosevi or sofosbuvir + Mavyret

❑ Vosevi 400/100/100 mg, one tablet daily + weight-based RBV for 24 weeks

GT 3 only: sofosbuvir/NS5A (e.g. Harvoni)

❑ Vosevi 400/100/100 mg, one tablet daily + weight-based RBV for 12 weeks

Re-infection of Allograft Liver after Transplant

DAA-treatment naïve, no decompensated cirrhosis

❑ Mavyret 100/40 mg, three (3) tablets daily for 12 weeks

❑ sofosbuvir/velpatasvir 400/100 mg, one tablet daily for 12 weeks

DAA-treatment experienced, no decompensated cirrhosis

❑ Vosevi 400/100/100 mg, one tablet daily for 12 weeks

IF multiple negative baseline characteristics, consider

❑ Vosevi 400/100/100 mg, one tablet daily + low dose RBV for 12 weeks
Treatment naïve, decompensated cirrhosis ❑ sofosbuvir/velpatasvir 400/100 mg, one tablet daily + low dose RBV for 12 weeks
Treatment experienced, decompensated cirrhosis (Child-Pugh B or C ONLY) ❑ sofosbuvir/velpatasvir 400/100 mg, one tablet daily + low dose RBV for 24 weeks
Decompensated Cirrhosis
No prior sofosbuvir or NS5A failure ❑ sofosbuvir/velpatasvir 400/100 mg + weight-based RBV daily for 12 weeks (low dose RBV recommended for Child-Pugh class C cirrhosis) ❑ sofosbuvir/velpatasvir 400/100 mg daily for 24 weeks (will be approved only for patients with documented ineligibility for RBV)
Prior sofosbuvir or NS5A failure ❑ sofosbuvir/velpatasvir 400/100 mg + weight-based RBV daily for 24 weeks (low dose RBV if Child-Pugh C)

3 . Revision History

Date	Notes
11/29/2021	Updated auth duration for Pegasys and ribavirin per state criteria.

Prior Authorization Guideline

GL-99012 Infectious Disease Agents, Antivirals - HIV

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: Brand Ziagen, generic abacavir soln, Brand Trizivir, generic abacavir/lamivudine/zidovudine, Aptivus, Edurant, generic efavirenz/lamivudine/tenofovir, generic emtricitabine, Brand Lexiva, generic fosamprenavir, Fuzeon, Brand Intelence, generic etravirine, Brand Epivir (not HBV), generic lamivudine (not HBV), generic lamivudine/zidovudine, Brand Combivir, generic lopinavir/ritonavir, nevirapine, Brand Norvir soln/pack, generic ritonavir, Selzentry, Stavudine, Stribild, Tybost, Viracept, Brand Epzicom, Brand Reyataz, Brand Sustiva, Brand Atripla, Brand Truvada, Brand Retrovir caps/syrup	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - ONE of the following:

1.1 Patient cannot be changed to a preferred* medication due to ONE of the following:

- Allergy to preferred medications
- Contraindication to preferred recommended regimens
- History of unacceptable/toxic side effects to preferred medications

OR

1.2 Patient has had a therapeutic trial of 30 days with at least ONE preferred* medication

AND

2 - If applicable, the request must address the patient's inability to use the individual components

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Rukobia	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has been diagnosed with multidrug-resistant HIV-1 (human immunodeficiency virus) infection

Product Name: Symtuza	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient cannot be changed to a preferred* medication due to ONE of the following:

- Allergy to preferred medications
- Contraindication to preferred recommended regimens
- History of unacceptable/toxic side effects to preferred medications

OR

1.2 Patient has had a therapeutic trial of 30 days with at least ONE preferred* medication

AND

2 - Documented clinical justification for patient inability to use the individual components (Prezcobix and Descovy)

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
11/30/2021	Updated drug list, all criteria, and notes. Added Rukobia criteria.

Prior Authorization Guideline

GL-104060 Infectious Disease Agents: Antifungals for Onychomycosis & Systemic Infections

Formulary

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Brand Sporanox capsule & oral soln, Brand Sporanox Pulsepak, generic itraconazole 100mg cap, generic itraconazole oral soln, Tolsura, generic terbinafine tab, Cresemba, Noxafil susp, Brand Noxafil tab, generic posaconazole DR tab, Oravig, Brand Vfend susp & tab, generic voriconazole susp & tab, Brexafemme	
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following **

- An allergy to preferred medications
- A contraindication to, or drug-drug interaction with, preferred medications***

• A history of unacceptable or toxic side effects to preferred medications **OR** **2** - The patient has a serious illness that causes them to be immunocompromised [i.e. AIDS, cancer, organ (solid or non-solid) transplant]. **OR** **3** - Patient has had a therapeutic failure to no less than a 7 day trial of one preferred medication ** **OR** **4** - For completion of a course of therapy that was initiated in the hospital, or other similar location **OR** **5** - For completion of a course of therapy for a patient who just became Medicaid eligible and is currently on the requested medication	
Notes	* Approval Length - For the duration of the prescription (up to 180 days) **PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP *** Drug interactions (inhibition of CYP450 system) Ketoconazole > Itraconazole> Voriconazole >Fluconazole *NOTE: If the request is for a diagnosis other than fungal infection, please refer the case to a pharmacist. An off label use may be approvable for a medication such as Nizoral® for advanced prostate cancer or for Cushing's Syndrome when standard treatments have failed.

2 . Revision History

Date	Notes
2/24/2022	Added Brexafemme. Cleaned up GPI list.

Prior Authorization Guideline

GL-57119 Infectious Disease Agents: Antibiotics - Quinolones

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2020

1 . Criteria

Product Name: Brand Cipro susp, generic ciprofloxacin susp, moxifloxacin, Baxdela	
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient has an allergy to preferred medications

OR

1.2 Patient has a contraindication or drug interaction with preferred medications

OR

1.3 Patient has a history of unacceptable/toxic side effects to preferred medications

OR

2 - BOTH of the following:

2.1 The infection is caused by an organism resistant to preferred medications

AND

2.2 Submission of documentation of diagnosis and culture and sensitivity reports

OR

3 - Patient has had a therapeutic failure to a 3 day trial of one preferred medication*

OR

4 - The requested medication was initiated in the hospital and the request is to complete the course of therapy

OR

5 - The prescriber expresses concern over safety issues of a preferred agent

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
11/20/2019	New Guideline created.

Prior Authorization Guideline

GL-77574 Infectious Disease Agents: Antibiotics – Tetracyclines

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2021

1 . Criteria

Product Name: Brand Doryx, generic doxycycline delayed release tablets, Doryx MPC, Brand Oracea, generic doxycycline delayed release capsules, Brand Acticlate, generic doxycycline hyclate tablets, generic doxycycline monohydrate capsules, generic doxycycline monohydrate tablets, generic minocycline extended release (ER), Minolira ER, Seysara, Brand Solodyn ER, Ximino	
Approval Length	30 Day(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient cannot be changed to a preferred medication due to ONE of the following*:	

1.1 Patient has an allergy to preferred medications

OR

1.2 Patient has a contraindication to, or drug interaction with, preferred medications

OR

1.3 Patient has a history of unacceptable/toxic side effects to preferred medications

OR

2 - The infection is caused by an organism resistant to preferred medications (Note diagnosis and any culture and sensitivity reports)

OR

3 - Patient has had a therapeutic failure to a 3 day trial of ONE preferred medication

OR

4 - The requested medication was initiated in the hospital and the request is to complete the course of therapy

Notes	*NOTE: PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Demeclocycline	
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient cannot be changed to a preferred medication due to ONE of the following*:

1.1.1 Patient has an allergy to preferred medications

OR

1.1.2 Patient has a contraindication to, or drug interaction with, preferred medications

OR

1.1.3 Patient has a history of unacceptable/toxic side effects to preferred medications

OR

1.2 The infection is caused by an organism resistant to preferred medications (Note diagnosis and any culture and sensitivity reports)

OR

1.3 Patient has had a therapeutic failure to a 3 day trial of ONE preferred medication

OR

1.4 The requested medication was initiated in the hospital and the request is to complete the course of therapy

AND

2 - Doxycycline, minocycline or tetracycline are inappropriate to treat the current medical condition clinically

Notes	*NOTE: PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Nuzyra	
Diagnosis	Community-Acquired Bacterial Pneumonia (CABP), Acute Bacterial Skin and Skin Structure Infection (ABSSSI)
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

1.1 Community-Acquired Bacterial Pneumonia (CABP) with prior failure of other first line agent

OR

1.2 Acute Bacterial Skin and Skin Structure Infection (ABSSSI) with prior failure of other first line agent

AND

2 - ONE of the following:

2.1 Patient cannot be changed to a preferred medication due to ONE of the following*:

2.1.1 Patient has an allergy to preferred medications

OR

2.1.2 Patient has a contraindication to, or drug interaction with, preferred medications

OR

2.1.3 Patient has a history of unacceptable/toxic side effects to preferred medications

OR

2.2 The infection is caused by an organism resistant to preferred medications (Note diagnosis and any culture and sensitivity reports)

OR

2.3 The requested medication was initiated in the hospital and the request is to complete the course of therapy

Notes	*NOTE: PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: brand Vibramycin suspension, generic doxycycline suspension	
Approval Length	30 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient is 12 years of age or under

OR

1.2 Patient is greater than 12 years of age and ONE of the following:

1.2.1 Patient has had a therapeutic failure to a 3 day trial of ONE preferred medication

OR

1.2.2 Patient cannot be changed to a preferred medication due to ONE of the following*:

- Patient has an allergy to preferred medications
- Patient has a contraindication to, or drug interaction with, preferred medications

• Patient has a history of unacceptable/toxic side effects to preferred medications **OR** **1.2.3** The infection is caused by an organism resistant to preferred medications (Note diagnosis and any culture and sensitivity reports) **OR** **1.2.4** The requested medication was initiated in the hospital and the request is to complete the course of therapy	
Notes	*NOTE: PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
11/25/2020	Added Vibramycin suspension criteria

Prior Authorization Guideline

GL-56929 Infectious Disease Agents: Antivirals - Herpes

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2020

1 . Criteria

Product Name: Famciclovir*, Sitavig*	
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has had therapeutic failure to a 3 day trial of ONE preferred medication

OR

2 - Patient has ONE of the following: **2.1** Allergy to preferred medications **OR** **2.2** Contraindication or drug interaction with preferred medications **OR** **2.3** History of unacceptable/toxic side effects to preferred medications

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
11/14/2019	C&S Implementation

Prior Authorization Guideline

GL-97349 Inlyta

Formulary

Formulary Note

Guideline Note:

Effective Date:	12/1/2021

1 . Criteria

Product Name: Inlyta	
Diagnosis	Advanced Renal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of renal cell cancer	

AND

2 - One of the following:

2.1 Disease has relapsed

OR

2.2 Diagnosis of Stage IV disease

Product Name: Inlyta	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnosis:

- Follicular Carcinoma
- Hürthle Cell Carcinoma
- Papillary Carcinoma

AND

2 - ONE of the following:

- Unresectable recurrent
- Persistent locoregional disease
- Metastatic disease

AND

3 - Disease is refractory to radioactive iodine treatment

Product Name: Inlyta	
Diagnosis	Advanced Renal Cell Carcinoma, Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Inlyta therapy	

Product Name: Inlyta	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Inlyta will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	

Product Name: Inlyta	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Inlyta therapy	

2 . Revision History

Date	Notes
10/26/2021	Updated GPI's

Prior Authorization Guideline

GL-80147 Inqovi

Formulary

Formulary Note

Guideline Note:

Effective Date:	3/1/2021

1 . Criteria

Product Name: Inqovi	
Diagnosis	Myelodysplastic Syndrome (MDS), Chronic Myelomonocytic Leukemia (CMML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - One of the following:	

1.1 Both of the following:

1.1.1 Diagnosis of myelodysplastic syndrome (MDS)

AND

1.1.2 Patient is intermediate-1, intermediate-2, or high-risk per the International Prognostic Scoring System (IPSS)

OR

1.2 Diagnosis of chronic myelomonocytic leukemia (CMML)

Product Name: Inqovi	
Diagnosis	Myelodysplastic Syndrome (MDS), Chronic Myelomonocytic Leukemia (CMML)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Inqovi therapy

Product Name: Inqovi	
Diagnosis	NCCN Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - The use of Inqovi is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Inqovi	
Diagnosis	NCCN Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - There is documentation of positive clinical response to Inqovi therapy

Prior Authorization Guideline

GL-105816 Inrebic

Formulary

Formulary Note

Guideline Note:

Effective Date:	6/1/2022

1 . Criteria

Product Name: Inrebic	
Diagnosis	Myelofibrosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Primary myelofibrosis

OR

1.2 Post-polycythemia vera myelofibrosis

OR

1.3 Post-essential thrombocythemia myelofibrosis

AND

2 - ONE of the following:

2.1 History of failure, contraindication, or intolerance to Jakafi (ruxolitinib)

OR

2.2 Patient is currently on Inrebic therapy

Product Name: Inrebic	
Diagnosis	Myelofibrosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation that the patient has evidence of symptom improvement or reduction in spleen volume while on Inrebic

Product Name: Inrebic	
Diagnosis	Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia

AND

2 - Patient has a JAK2 (Janus kinase 2) rearrangement

AND

3 - ONE of the following:

3.1 History of failure, contraindication, or intolerance to Jakafi (ruxolitinib)

OR

3.2 Patient is currently on Inrebic therapy

Product Name: Inrebic	
Diagnosis	Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Inrebic therapy

Product Name: Inrebic	
Diagnosis	NCCN Recommended Regimens

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Inrebic	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Inrebic therapy

Prior Authorization Guideline

GL-96480 Insulin Pen Needles and Syringes

Formulary

Formulary Note

Guideline Note:

Effective Date:	12/1/2021

1 . Criteria

Product Name: Non-preferred insulin pen needles and insulin syringes	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - History of failure to a preferred* BD (Becton Dickinson) insulin pen needle or syringe

OR

2 - Physician has provided documentation as to why the patient is unable to use a preferred* BD product (document rationale)	
Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html

Product Name: All insulin pen needles and insulin syringes	
Diagnosis	Criteria for exceeding 6 pen needles or syringes per day*
Approval Length	12 month(s)
Guideline Type	Quantity Limit
Approval Criteria **1** - Physician confirmation that the patient requires a greater quantity because of more frequent delivery of insulin	
Notes	*The quantity limit for both pen needles and syringes is 6 of each per day.

Prior Authorization Guideline

GL-100018 Intron A

Formulary

Formulary Note

Guideline Note:

Effective Date:	2/1/2022

1 . Criteria

Product Name: Intron A	
Diagnosis	Hepatitis B
Approval Length	48 Week(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has diagnosis of chronic Hepatitis B infection	

AND

2 - Patient does not have decompensated liver disease (defined as Child-Pugh Class B or C)

Product Name: Intron A	
Diagnosis	Hepatitis C
Approval Length	48 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has diagnosis of chronic Hepatitis C infection

AND

2 - Patient does not have decompensated liver disease (defined as Child-Pugh Class B or C)

AND

3 - Intron A will be used as part of a combination antiviral treatment regimen

Product Name: Intron A	
Diagnosis	Diagnoses other than Hepatitis
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

- Hairy cell leukemia
- Malignant melanoma
- Follicular lymphoma

- Condylomata acuminata (genital or perianal)
- AIDS (Acquired immunodeficiency syndrome)-related Kaposi's sarcoma
- Giant cell tumors of the bone
- Mycosis fungoides / Sézary syndrome
- Primary cutaneous CD30+ T-cell lymphoproliferative disorders
- Adult T-cell leukemia/lymphoma

Product Name: Intron A	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Intron A	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
12/17/2021	Removed discontinued product, Sylatron. Updated criteria to align wit h label and NCCN guidelines. Removed inactive GPIs

Prior Authorization Guideline

GL-96944 Iressa

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: Iressa	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of metastatic or recurrent non-small cell lung cancer (NSCLC)	

AND

2 - ONE of the following:

- Tumors are positive for epidermal growth factor receptor (EGFR) exon 19 deletions
- Tumors are positive for exon 21 (L858R) substitution mutations
- Tumors are positive for a known sensitizing EGFR mutation (e.g., in-frame exon 20 insertions, exon 18 G719 mutation, exon 21 L861Q mutation)

Product Name: Iressa	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Iressa therapy

Product Name: Iressa	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of central nervous system (CNS) cancer with metastatic lesions

AND

2 - Iressa is active against primary (NSCLC) tumor with a known epidermal growth factor receptor (EGFR) sensitizing mutation

Product Name: Iressa	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Iressa therapy

Product Name: Iressa	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Iressa will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Iressa	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Iressa therapy

2 . Revision History

Date	Notes
10/19/2021	Update

Prior Authorization Guideline

GL-109719 Iron Chelators

Formulary

Formulary Note

Guideline Note:

Effective Date:	9/1/2022

1 . Criteria

Product Name: Brand Exjade, Brand Jadenu, generic deferasirox	
Diagnosis	Chronic Iron Overload due to Blood Transfusion
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic iron overload (e.g., sickle cell anemia, thalassemia, etc.) due to blood transfusion

Product Name: Brand Exjade, Brand Jadenu, generic deferasirox	
Diagnosis	Chronic Iron Overload due to Blood Transfusion
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Brand Ferriprox, generic deferiprone	
Diagnosis	Chronic Iron Overload due to Blood Transfusion
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following

1.1 Diagnosis of transfusional iron overload due to thalassemia syndromes, sickle cell disease or other anemias

AND

1.2 Ferriprox (deferiprone) will not be used for the treatment of transfusional iron overload due to myelodysplastic syndrome or Diamond Blackfan anemia

Product Name: Brand Ferriprox, generic deferiprone	
Diagnosis	Chronic Iron Overload due to Blood Transfusion
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Brand Exjade, Brand Jadenu, generic deferasirox	
Diagnosis	Chronic Iron Overload in Non-Transfusion Dependent Thalassemia Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of chronic iron overload in non-transfusion dependent thalassemia (NTDT) syndrome

AND

1.2 Patient has liver iron (Fe) concentration (LIC) levels consistently greater than or equal to 5 mg Fe per gram of dry weight prior to initiation of treatment with Exjade (deferasirox) or Jadenu (deferasirox)

AND

1.3 Patient has serum ferritin levels consistently greater than 300 micrograms per liter prior to initiation of treatment with Exjade (deferasirox) or Jadenu (deferasirox)

Product Name: Brand Exjade, Brand Jadenu, generic deferasirox	
Diagnosis	Chronic Iron Overload in Non-Transfusion Dependent Thalassemia Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
7/22/2022	Added generic deferiprone 1000 mg tablet. Clarified listing of generics throughout guideline.

Prior Authorization Guideline

GL-89460 Isturisa

Formulary

Formulary Note

Guideline Note:

Effective Date:	9/1/2021

1 . Criteria

Product Name: Isturisa	
Diagnosis	Cushing's Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Cushing's disease	

AND

2 - ONE of the following:

- Patient is not a candidate for pituitary surgery
- Pituitary surgery has not been curative

Product Name: Isturisa	
Diagnosis	Cushing's Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive response to Isturisa therapy

2 . Revision History

Date	Notes
7/6/2021	Copied from NY. Removed NCCN language.

Prior Authorization Guideline

GL-99871 Jakafi

Formulary

Formulary Note

Guideline Note:

Effective Date:	2/1/2022

1 . Criteria

Product Name: Jakafi	
Diagnosis	Myelofibrosis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

1.1 Primary myelofibrosis

OR

1.2 Post-polycythemia vera myelofibrosis

OR

1.3 Post-essential thrombocythemia myelofibrosis

Product Name: Jakafi	
Diagnosis	Polycythemia Vera
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of polycythemia vera

AND

2 - History of failure, inadequate response, contraindication, or intolerance to ONE of the following:

2.1 Hydroxyurea

OR

2.2 Interferon therapy (e.g., Intron A, Pegasys)

Product Name: Jakafi	
Diagnosis	Myelofibrosis, Polycythemia Vera
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation that patient has evidence of symptom improvement or reduction in spleen volume while on Jakafi*

Notes	* If documentation does not provide evidence of symptom improveme nt or reduction in spleen volume while on Jakafi, authorization will be i ssued for 2 months to allow for dose titration with discontinuation of th erapy.

Product Name: Jakafi	
Diagnosis	Graft versus host disease (GVHD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of graft versus host disease (GVHD)

AND

2 - Disease is steroid refractory

Product Name: Jakafi	
Diagnosis	Graft versus host disease (GVHD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation that patient has symptom improvement while on Jakafi

Product Name: Jakafi	
Diagnosis	Myeloid-Lymphoid Neoplasms
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia

AND

2 - Patient has a JAK2 rearrangement

Product Name: Jakafi	
Diagnosis	Myelodysplastic Syndromes
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following

1.1 Diagnosis of chronic myelomonocytic leukemia (CMML)-2

AND

1.2 Used in combination with a hypomethylating agent (e.g., azacitidine, decitabine)

OR

2 - Diagnosis of BCR-ABL negative atypical chronic myeloid leukemia (aCML)

Product Name: Jakafi	
Diagnosis	Myeloid-Lymphoid Neoplasms, Myelodysplastic Syndromes
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Jakafi therapy

Product Name: Jakafi	
Diagnosis	Pediatric Acute Lymphoblastic Leukemia
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pediatric acute lymphoblastic leukemia

AND

2 - Used as a component of induction or consolidation therapy

Product Name: Jakafi	
Diagnosis	Immunotherapy-Related Toxicities
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of CAR-T induced G4 cytokine release syndrome

AND

2 - Disease is refractory to high-dose corticosteroids and anti-IL-6 therapy (e.g., Actemra [tocilizumab])

Product Name: Jakafi	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Jakafi will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Jakafi	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Jakafi therapy

2 . Revision History

Date	Notes

12/9/2021	Removed PegIntron from example list. Added criteria for Pediatric Acute Lymphoblastic Leukemia and Immunotherapy-Related Toxicities

Prior Authorization Guideline

GL-72785 Jynarque

Formulary

Formulary Note

Guideline Note:

Effective Date:	11/1/2020

1 . Criteria

Product Name: Jynarque, Jynarque Pak	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of autosomal dominant polycystic kidney disease (ADPKD)	

Product Name: Jynarque, Jynarque Pak

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Jynarque therapy

2 . Revision History

Date	Notes
9/2/2020	Added new Jynarque GPIs

Prior Authorization Guideline

GL-62819 Keveyis

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Keveyis	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of primary hyperkalemic periodic paralysis or related variant

OR **1.2** Diagnosis of primary hypokalemic periodic paralysis or related variant

Product Name: Keveyis	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Keveyis therapy	

2 . Revision History

Date	Notes
3/10/2020	New Program

Prior Authorization Guideline

GL-104897 Kisqali

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/1/2022

1 . Criteria

Product Name: Kisqali	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced, recurrent, or metastatic breast cancer

AND

2 - BOTH of the following:

- Disease is hormone receptor (HR)-positive
- Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

3 - BOTH of the following:

3.1 ONE of the following:

- Used in combination with an aromatase inhibitor [e.g., anastrozole, letrozole, exemestane]
- Used in combination with Faslodex (fulvestrant)

AND

3.2 ONE of the following:

- History of failure, contraindication, or intolerance to Verzenio (abemaciclib)
- Patient is currently on Kisqali therapy

Product Name: Kisqali	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Kisqali therapy

Product Name: Kisqali	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Kisqali will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Kisqali	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Kisqali therapy

Prior Authorization Guideline

GL-104902 Kisqali Femara Co-Pack

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/1/2022

1 . Criteria

Product Name: Kisqali Femara Co-Pack	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced, recurrent, or metastatic breast cancer

AND

2 - Disease is hormone receptor (HR)-positive

AND

3 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

4 - ONE of the following:

4.1 History of failure, contraindication, or intolerance to Verzenio (abemaciclib) plus an aromatase inhibitor (e.g., anastrozole, letrozole)

OR

4.2 Patient is currently on Kisqali Femara Co-Pack therapy

Product Name: Kisqali Femara Co-Pack	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Kisqali Femara Co-Pack therapy

Product Name: Kisqali Femara Co-Pack	
Diagnosis	NCCN Recommended Regimen

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Kisqali Femara Co-Pack will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Kisqali Femara Co-Pack	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Kisqali Femara Co-Pack therapy

Prior Authorization Guideline

GL-56563 Korlym

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2020
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Korlym	
Diagnosis	Endogenous Cushing's Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - ALL of the following:

1.1 Diagnosis of Endogenous Cushing's Syndrome (i.e., hypercortisolism is not a result of chronic administration of high dose glucocorticoids)

AND

1.2 ONE of the following:

- Diagnosis of type 2 diabetes mellitus
- Diagnosis of glucose intolerance

AND

1.3 ONE of the following:

- Patient has failed surgery
- Patient is not a candidate for surgery

Product Name: Korlym	
Diagnosis	Endogenous Cushing's Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of ONE of the following:

- Patient has improved glucose tolerance while on Korlym therapy
- Patient has stable glucose tolerance while on Korlym therapy

2 . Revision History

Date	Notes
11/6/2019	New Guideline.

Prior Authorization Guideline

GL-94071 Koselugo

Formulary

Formulary Note

Guideline Note:

Effective Date:	11/1/2021

1 . Criteria

Product Name: Koselugo	
Diagnosis	Neurofibromatosis Type 1
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of neurofibromatosis type 1	

AND

2 - Patient has plexiform neurofibromas that are BOTH of the following:

- Inoperable
- Causing significant morbidity (e.g., disfigurement, motor dysfunction, pain, airway dysfunction, visual impairment, bladder/bowel dysfunction)

Product Name: Koselugo	
Diagnosis	Pilocytic Astrocytoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent or progressive pilocytic astrocytoma

AND

2 - Presence of BRAF fusion or BRAF V600E activating mutations

AND

3 - Used as monotherapy

Product Name: Koselugo	
Diagnosis	Neurofibromatosis Type 1, Pilocytic Astrocytoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Koselugo therapy

Product Name: Koselugo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Koselugo will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Koselugo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Koselugo therapy

Prior Authorization Guideline

GL-90041 Kuvan

Formulary

Formulary Note

Guideline Note:

Effective Date:	10/1/2021

1 . Criteria

Product Name: generic sapropterin, Brand Kuvan	
Diagnosis	Phenylketouria (PKU)
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of phenylketonuria (PKU)	

Prior Authorization Guideline

GL-78264 Lampit

Formulary

Formulary Note

Guideline Note:

Effective Date:	2/1/2021

1 . Criteria

Product Name: Lampit	
Diagnosis	Chagas disease (American trypanosomiasis)
Approval Length	60 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Chagas disease (American trypanosomiasis) caused by Trypanosoma cruzi

Prior Authorization Guideline

GL-105091 Lenvima

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/1/2022

1 . Criteria

Product Name: Lenvima	
Diagnosis	Renal Cell Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced renal cell carcinoma

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 History of failure, contraindication, or intolerance to prior anti-angiogenic therapy [e.g., Avastin (bevacizumab), Votrient (pazopanib), Sutent (sunitinib), Nexavar (sorafenib)]

AND

2.1.2 Used in combination with Afinitor (everolimus)

OR

2.2 Used in combination with Keytruda (pembrolizumab)

Product Name: Lenvima	
Diagnosis	Renal Cell Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Lenvima therapy

AND

2 - Used in combination with Afinitor (everolimus) or Keytruda (pembrolizumab)

Product Name: Lenvima	
Diagnosis	Thyroid Cancer

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ALL of the following:

1.1.1 Diagnosis of ONE of the following:

- Follicular carcinoma
- Hürthle cell carcinoma
- Papillary carcinoma

AND

1.1.2 ONE of the following:

- Unresectable or locally recurrent disease
- Metastatic disease
- Persistent locoregional disease

AND

1.1.3 ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

AND

1.1.4 ONE of the following:

- Disease is refractory to radioactive iodine
- Distant metastatic disease not amenable to radioactive iodine treatment

OR

1.2 ALL of the following:

1.2.1 Diagnosis of medullary thyroid carcinoma

AND

1.2.2 ONE of the following:

- Disease is progressive
- Disease is symptomatic with distant metastases

AND

1.2.3 History of failure, contraindication, or intolerance to ONE of the following:

- Caprelsa (vandetanib)
- Cometriq (cabozantinib)

Product Name: Lenvima	
Diagnosis	Hepatobiliary Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

1.1.1 Diagnosis of hepatocellular carcinoma

AND

1.1.2 Disease is ONE of the following:

- Unresectable
- Metastatic

OR

1.2 ALL of the following:

1.2.1 Diagnosis of biliary tract cancer

AND

1.2.2 Disease is ONE of the following:

- Unresectable
- Metastatic

AND

1.2.3 Disease has progressed on or after systemic treatment

AND

1.2.4 Used in combination with Keytruda (pembrolizumab)

Product Name: Lenvima	
Diagnosis	Adenoid Cystic Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent adenoid cystic carcinoma

Product Name: Lenvima	
Diagnosis	Thymic Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of thymic carcinoma

AND

2 - ONE of the following:

- Used for postoperative treatment
- Disease is unresectable or potentially resectable
- Disease is metastatic

Product Name: Lenvima	
Diagnosis	Thyroid Cancer, Hepatobiliary Cancer, Adenoid Cystic Carcinoma, Thymic Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Lenvima therapy

Product Name: Lenvima	
Diagnosis	Endometrial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of endometrial carcinoma

AND

2 - Used in combination with Keytruda (pembrolizumab)

Product Name: Lenvima	
Diagnosis	Endometrial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Lenvima therapy

AND

2 - Used in combination with Keytruda (pembrolizumab)

Product Name: Lenvima	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Lenvima will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Lenvima	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Lenvima therapy

2 . Revision History

Date	Notes
3/23/2022	Updated renal cell cancer reauthorization to include combination use of Afinitor (everolimus) or Keytruda (pembrolizumab).

Prior Authorization Guideline

GL-103124 Livmarli

Formulary

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Livmarli	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Alagille syndrome (ALGS) confirmed by presence of the JAG1 or Notch2 gene mutation

AND

2 - Evidence of cholestasis by at least ONE of the following:

- Total serum bile acid > 3x ULN (upper limit of normal) for age
- Conjugated bilirubin > 1 mg/dL (milligrams/deciliter)
- Fat soluble vitamin deficiency otherwise unexplainable
- GGT (gamma-glutamyl transferase) > 3x ULN for age
- Intractable pruritus explainable only by liver disease

AND

3 - Patient is experiencing moderate to severe pruritus

AND

4 - Patient has had an inadequate response to at least TWO medications to treat pruritus (e.g., ursodeoxycholic acid, rifampin, cholestyramine, colesevelam)

AND

5 - Prescribed by a hepatologist

Product Name: Livmarli	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Livmarli therapy (e.g., reduced serum bile acids, reduced pruritis severity score)

AND **2** - Prescribed by a hepatologist

2 . Revision History

Date	Notes
1/28/2022	Update

Prior Authorization Guideline

GL-104786 Livtencity

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/1/2022

1 . Criteria

Product Name: Livtencity	
Approval Length	2 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of post-transplant cytomegalovirus (CMV) infection or CMV disease

AND

2 - CMV infection or disease is refractory to treatment (with or without genotypic resistance) to one of the following:

- Ganciclovir
- Valganciclovir
- Cidofovir
- Foscarnet

AND

3 - Patient will not be utilizing the requested medication in combination with ganciclovir or valganciclovir.

Prior Authorization Guideline

GL-81115 Lokelma, Veltassa

Formulary

Formulary Note

Guideline Note:

Effective Date:	4/1/2021

1 . Criteria

Product Name: Lokelma, Veltassa	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-life threatening hyperkalemia

AND

2 - Where clinically appropriate, medications known to cause hyperkalemia [e.g., angiotensin-converting enzyme inhibitor, angiotensin II receptor blocker, aldosterone antagonist, non-steroidal anti-inflammatory drugs (NSAIDs)] have been discontinued or reduced to the lowest effective dose

AND

3 - Where clinically appropriate, loop or thiazide diuretic therapy for potassium removal has failed

AND

4 - Patient follows a low potassium diet (less than or equal to 3 grams per day)

Product Name: Lokelma, Veltassa	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a positive clinical response to Lokelma or Veltassa therapy

AND

2 - Patient continues to require treatment for hyperkalemia

AND

3 - Where clinically appropriate, medications known to cause hyperkalemia [e.g., angiotensin-converting enzyme inhibitor, angiotensin II receptor blocker, aldosterone antagonist, non-

steroidal anti-inflammatory drugs (NSAIDs)] have been discontinued or reduced to the lowest effective dose

AND

4 - Patient follows a low potassium diet (less than or equal to 3 grams per day)

Prior Authorization Guideline

GL-95057 Lonsurf

Formulary

Formulary Note

Guideline Note:

Effective Date:	9/29/2021

1 . Criteria

Product Name: Lonsurf	
Diagnosis	Colorectal Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic colorectal cancer (mCRC)

AND

2 - History of failure, contraindication, or intolerance to treatment with ALL of the following:

- Fluoropyrimidine-based chemotherapy
- Oxaliplatin-based chemotherapy
- Irinotecan-based chemotherapy
- Anti-vascular endothelial growth factor (VEGF) biological therapy

AND

3 - ONE of the following:

3.1 Tumors is RAS mutant-type

OR

3.2 BOTH of the following:

- Tumor is RAS wild-type
- History of failure, contraindication, or intolerance to anti-EGFR (epidermal growth factor receptor) therapy

Product Name: Lonsurf	
Diagnosis	Gastric/Gastroesophageal Junction Adenocarcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Metastatic gastric cancer
- Metastatic gastroesophageal junction adenocarcinoma

AND

2 - History of failure, contraindication, or intolerance to treatment with at least TWO prior lines of chemotherapy that consisted of the following agents:

- Fluoropyrimidine (e.g., fluorouracil)
- Platinum (e.g., carboplatin, cisplatin, oxaliplatin)
- Taxane (e.g., docetaxel, paclitaxel) or irinotecan
- Human epidermal growth factor receptor 2 (HER2)/neu-targeted therapy (e.g., trastuzumab) (if HER2 overexpression)

Product Name: Lonsurf	
Diagnosis	Colorectal Cancer, Gastric/Gastroesophageal Junction Adenocarcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Lonsurf therapy

Product Name: Lonsurf	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Lonsurf

Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Lonsurf therapy

Prior Authorization Guideline

GL-104852 Lorbrena

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/1/2022

1 . Criteria

Product Name: Lorbrena	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of non-small cell lung cancer (NSCLC)	

AND

2 - One of the following:

2.1 Disease is Both of the following:

- Recurrent, advanced, or metastatic
- Anaplastic lymphoma kinase (ALK)-positive

OR

2.2 Both of the following:

2.2.1 Disease is BOTH of the following:

- Recurrent, advanced, or metastatic
- ROS proto-oncogene 1 (ROS1)-positive

AND

2.2.2 Disease has progressed on at least ONE of the following therapies:

- Rozlytrek (entrectinib)
- Xalkori (crizotinib)
- Zykadia (ceritinib)

Product Name: Lorbrena	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Lorbrena therapy

Product Name: Lorbrena	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Lorbrena will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Lorbrena	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Lorbrena therapy

Prior Authorization Guideline

GL-90116 Lumakras

Formulary

Formulary Note

Guideline Note:

Effective Date:	10/1/2021

1 . Criteria

Product Name: Lumakras	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of non-small cell lung cancer (NSCLC)	

AND

2 - Disease is ONE of the following:

- Locally advanced
- Metastatic

AND

3 - Tumor is KRAS G12C (gene)-mutated

AND

4 - Patient has received at least one prior systemic therapy (e.g., immune checkpoint inhibitor, platinum-based chemotherapy)

Product Name: Lumakras	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Lumakras therapy

Product Name: Lumakras	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Lumakras	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Lumakras therapy

Prior Authorization Guideline

GL-109236 Lupkynis

Formulary

Formulary Note

Guideline Note:

Effective Date:	9/1/2022

1 . Criteria

Product Name: Lupkynis	
Diagnosis	Active Lupus Nephritis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of active lupus nephritis	

AND

2 - Provider attests to ONE of the following:

- Diagnosis is biopsy proven
- Biopsy is contraindicated in the patient

AND

3 - Provider attests to ONE of the following:

3.1 Clinical progression (e.g., worsening of proteinuria or serum creatinine) after 3 months of induction therapy with immunosuppressive agents (e.g., mycophenolate, cyclophosphamide, methylprednisolone), as confirmed by claims history or submission of medical records

OR

3.2 Failure to respond after 6 months of induction therapy with immunosuppressive agents (e.g., mycophenolate, cyclophosphamide, methylprednisolone), as confirmed by claims history or submission of medical records

AND

4 - Prescribed in combination with a background immunosuppressive therapy regimen (e.g., mycophenolate mofetil and corticosteroids)

AND

5 - Patient is NOT receiving Lupkynis in combination with any of the following:

- Cyclophosphamide
- Benlysta (belimumab)

AND

6 - Prescribed by ONE of the following:

- Nephrologist
- Rheumatologist

Product Name: Lupkynis	
Diagnosis	Active Lupus Nephritis
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Lupkynis therapy

AND

2 - Prescribed in combination with a background immunosuppressive therapy regimen (e.g., mycophenolate mofetil and corticosteroids)

AND

3 - Patient is NOT receiving Lupkynis in combination with any of the following:

- Cyclophosphamide
- Benlysta (belimumab)

AND

4 - Prescribed by ONE of the following:

- Nephrologist
- Rheumatologist

AND

5 - ONE of the following:

5.1 Patient has been on Lupkynis therapy for less than 12 months

OR

5.2 BOTH of the following:

5.2.1 Patient has completed 12 or more months of Lupkynis therapy

AND

5.2.2 The provider attests that the benefit of continuation of therapy exceeds the risk in light of the patient's treatment response and risk of worsening nephrotoxicity

Prior Authorization Guideline

GL-108405 Lynparza

Formulary

Formulary Note

Guideline Note:

Effective Date:	8/1/2022

1 . Criteria

Product Name: Lynparza	
Diagnosis	Breast Cancer (High Risk Early)
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of high risk early breast cancer	

AND

2 - Presence of deleterious or suspected deleterious germline breast cancer (BRCA)-mutations (gBRCAm)

AND

3 - Disease is human growth factor receptor 2 (HER2)-negative

AND

4 - ONE of the following:

4.1 Patient is hormone receptor (HR) negative

OR

4.2 BOTH of the following:

4.2.1 Patient is hormone receptor (HR) positive

AND

4.2.2 Patient is continuing concurrent treatment with endocrine therapy

AND

5 - Patient has been treated with neoadjuvant or adjuvant chemotherapy

AND

6 - Treatment duration has not exceeded 12 months of therapy

Product Name: Lynparza	
Diagnosis	Breast Cancer (Metastatic or Recurrent)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

1.1 Metastatic breast cancer

OR

1.2 Recurrent breast cancer

AND

2 - Presence of deleterious or suspected deleterious germline breast cancer (BRCA)-mutations (gBRCAm)

AND

3 - ONE of the following:

3.1 BOTH of the following:

3.1.1 Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

3.1.2 ONE of the following:

3.1.2.1 Disease is hormone receptor (HR) negative

OR

3.1.2.2 BOTH of the following:

3.1.2.2.1 Disease is hormone receptor (HR) positive

AND

3.1.2.2.2 ONE of the following:

- Disease has progressed on previous endocrine therapy
- Provider attestation that treatment with endocrine therapy is inappropriate

OR

3.2 Disease is human epidermal growth factor receptor 2 (HER2)-positive

Product Name: Lynparza	
Diagnosis	Ovarian Cancer (Maintenance Therapy)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Epithelial ovarian cancer
- Fallopian tube cancer
- Primary peritoneal cancer

AND

2 - Disease is advanced or recurrent

AND

3 - ONE of the following:

3.1 Patient has had a complete or partial response to platinum-based chemotherapy

OR

3.2 BOTH of the following:

3.2.1 Patient has had a complete or partial response to first-line platinum-based chemotherapy

AND

3.2.2 ONE of the following:

3.2.2.1 Presence of deleterious or suspected deleterious germline or somatic BRCA (breast cancer gene)-mutations

OR

3.2.2.2 BOTH of the following:

- Cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either a deleterious or suspected deleterious BRCA mutation or genomic instability
- Used in combination with bevacizumab (e.g., Avastin, Mvasi)

AND

4 - Request is for maintenance therapy

Product Name: Lynparza	
Diagnosis	Ovarian Cancer (Treatment)

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Epithelial ovarian cancer
- Fallopian tube cancer
- Primary peritoneal cancer

AND

2 - Disease is ONE of the following:

- Advanced
- Persistent
- Recurrent

AND

3 - Presence of deleterious or suspected deleterious germline BRCA (breast cancer gene)-mutation

AND

4 - Patient has been treated with two or more prior lines of chemotherapy

Product Name: Lynparza	
Diagnosis	Pancreatic Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pancreatic adenocarcinoma

AND

2 - Disease is metastatic

AND

3 - Presence of deleterious or suspected deleterious germline BRCA1/2 (breast cancer gene)-mutation

AND

4 - Disease has not progressed while receiving at least 16 weeks of a first-line platinum-based chemotherapy regimen

Product Name: Lynparza	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic castration-resistant prostate cancer

AND

2 - Presence of deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene mutations

AND

3 - Disease has progressed following prior treatment with ONE of the following:

- Enzalutamide (Xtandi)
- Abiraterone (e.g., Zytiga, Yonsa)

AND

4 - ONE of the following:

4.1 Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

OR

4.2 Patient has had bilateral orchiectomy

Product Name: Lynparza	
Diagnosis	Uterine Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of uterine sarcoma

AND

2 - The requested medication is NOT used as first-line therapy

Product Name: Lynparza	
Diagnosis	Breast Cancer (Metastatic or Recurrent), Ovarian Cancer (Maintenance or Treatment), Pancreatic Cancer, Prostate Cancer, Uterine Neoplasms

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Lynparza therapy

Product Name: Lynparza	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Lynparza	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Lynparza therapy

2 . Revision History

Date	Notes

6/20/2022	Added criteria for high risk early breast cancer per label. Clarified me tastatic and recurrent breast cancer in separate criteria. Added criteri a for uterine neoplasms per NCCN recommendations.

Prior Authorization Guideline

GL-62894 Lysteda

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Brand Lysteda, generic tranexamic acid	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of cyclic heavy menstrual bleeding	

2 . Revision History

Date	Notes
3/11/2020	C&S Implementation

Prior Authorization Guideline

GL-62069 MAT of Opioid Addiction-Lucemyra

Formulary

Formulary Note

Guideline Note:

Effective Date:	4/1/2020

1 . Criteria

Product Name: Lucemyra	
Diagnosis	Opioid Withdrawal
Approval Length	14 Day(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of opioid dependence or opioid use disorder	

AND

2 - 18 years of age or older

AND

3 - Patient is currently undergoing or is scheduled to undergo abrupt opioid discontinuation

AND

4 - Medical justification supports why an opioid taper (such as with buprenorphine or methadone) cannot be used

AND

5 - Patient meets ONE of the following:

5.1 Therapeutic failure of clonidine due to intolerable adverse effects or inability to reach maximal doses of clonidine due to adverse effects

OR

5.2 Documented history of intolerance to clonidine

OR

5.3 Contraindication to clonidine as specified in FDA (Food And Drug Administration) labeling

OR

5.4 Lucemyra (lofexidine) has already been initiated in an inpatient setting

AND **6** - Dose will not exceed 2.88 milligrams (16 tablets) per day

2 . Revision History

Date	Notes
2/11/2020	New Program

Prior Authorization Guideline

GL-107422 MAT therapy - Medication Assisted Treatment

Formulary

Formulary Note

Guideline Note:

Effective Date:	7/1/2022

1 . Criteria

Product Name: Brand Suboxone SL Film, generic buprenorphine/naloxone sublingual film, buprenorphine sublingual tablet, Zubsolv, buprenorphine/naloxone sublingual tablet	
Diagnosis	Patients less than 16 years of age*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The prescriber attests they are aware of FDA (Food and Drug Administration) labeling regarding use of MAT (Medication Assisted Treatment) products (Suboxone, buprenorphine, buprenorphine/naloxone, Zubsolv) in patients less than 16 years of age and feels the treatment with the requested product is medically necessary. (Document rationale for use)

Notes	*Up to 24 mg of buprenorphine equivalents/day will be authorized

Product Name: buprenorphine sublingual tablet	
Diagnosis	Patients greater than or equal to 16 years of age*
Approval Length	12 month(s)
Guideline Type	Prior Authorization*

Approval Criteria

1 - One of the following:

1.1 Patient has both of the following:

- Patient is male
- Patient has documented intolerance to naloxone

OR

1.2 Patient has both of the following:

- Patient is female
- Patient is greater than or equal to 16 years of age and less than or equal to 45 years of age

OR

1.3 Patient has all of the following:

1.3.1 Patient is female

AND

1.3.2 Patient is greater than 45 years of age

AND

1.3.3 One of the following: • Patient has documented intolerance to naloxone • Patient is pregnant or breast feeding

Notes	*Up to 24 mg of buprenorphine equivalents/day will be authorized

Product Name: Brand Suboxone SL Film, generic buprenorphine/naloxone sublingual film, buprenorphine sublingual tablet, Zubsolv, buprenorphine/naloxone sublingual tablet	
Diagnosis	Requests Exceeding 24 mg of buprenorphine equivalents/day
Approval Length	12 month(s)
Guideline Type	Quantity Limit
Approval Criteria **1** - Physician has provided rationale for needing to exceed the buprenorphine daily limit	

2 . Revision History

Date	Notes
5/24/2022	Removed inactive Bunavail and updated buprenorphine SL tablet GPI. Updated duration authorization per Ohio Department of Medicaid, safety edits in place for dosages over 24mg of buprenorphine equivalents/day. Rearranged and clarified criteria.

Prior Authorization Guideline

GL-105833 Mekinist

Formulary

Formulary Note

Guideline Note:

Effective Date:	6/1/2022

1 . Criteria

Product Name: Mekinist	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 One of the following:

1.1.1 Unresectable melanoma

OR

1.1.2 Metastatic melanoma

OR

1.1.3 Both of the following:

1.1.3.1 Prescribed as adjuvant therapy for melanoma involving the lymph node(s)

AND

1.1.3.2 Used in combination with Tafinlar (dabrafenib)

AND

1.2 Cancer is positive for BRAF V600 (gene) mutation

OR

2 - Distant metastatic uveal melanoma

Product Name: Mekinist	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is ONE of the following:

- Metastatic
- Advanced
- Recurrent

AND

3 - Cancer is positive for BRAF V600E (gene) mutation

AND

4 - Used in combination with Tafinlar (dabrafenib)

Product Name: Mekinist	
Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anaplastic thyroid cancer (ATC)

AND

2 - Cancer is positive for BRAF V600E (gene) mutation

AND

3 - Used in combination with Tafinlar (dabrafenib)

AND

4 - ONE of the following:

4.1 Disease is ONE of the following:

- Metastatic
- Locally advanced
- Unresectable

OR

4.2 Prescribed as adjuvant therapy following resection

Product Name: Mekinist	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Patient has metastatic brain lesions

AND

1.1.2 Mekinist is active against the primary tumor (melanoma)

OR

1.2 Both of the following:

1.2.1 Patient has ONE of the following:

- Pilocytic astrocytoma
- Pleomorphic xanthoastrocytoma (PXA)
- Ganglioglioma

AND

1.2.2 Incomplete resection, biopsy, or surgically inaccessible location

OR

1.3 Patient has ONE of the following:

- Recurrent anaplastic glioma
- Recurrent glioblastoma
- Recurrent or progressive low-grade disease glioma

AND

2 - Cancer is positive for BRAF V600E (gene) mutation

AND

3 - Used in combination with Tafinlar (dabrafenib)

Product Name: Mekinist	
Diagnosis	Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Epithelial Ovarian Cancer
- Fallopian Tube Cancer
- Primary Peritoneal Cancer

AND

2 - Persistent disease or recurrence of low-grade serous carcinoma

Product Name: Mekinist	
Diagnosis	Hepatobiliary Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Gallbladder cancer
- Extrahepatic Cholangiocarcinoma
- Intrahepatic Cholangiocarcinoma

AND

2 - Used as subsequent treatment after progression on or after systemic treatment

AND

3 - Disease is unresectable or metastatic

AND

4 - Cancer is positive for BRAF V600E (gene) mutation

AND

5 - Used in combination with Tafinlar (dabrafenib)

Product Name: Mekinist	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Langerhans Cell Histiocytosis
- Erdheim-Chester Disease
- Rosai-Dorfman Disease

AND

2 - ONE of the following:

- Mitogen-activated protein (MAP) kinase pathway mutation
- No detectable mutation
- Testing not available

Product Name: Mekinist	
Diagnosis	Melanoma, NSCLC, Thyroid Cancer, CNS Cancers, Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer, Hepatobiliary Cancers, Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Mekinist therapy

Product Name: Mekinist	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Mekinist	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Mekinist therapy

Prior Authorization Guideline

GL-94111 Mektovi

Formulary

Formulary Note

Guideline Note:

Effective Date:	11/1/2021

1 . Criteria

Product Name: Mektovi	
Diagnosis	Melanoma with BRAF mutation
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 ONE of the following diagnoses:

- Unresectable melanoma
- Metastatic melanoma

AND

1.2 Patient is positive for BRAFV600 mutation

AND

1.3 Used in combination with Braftovi (encorafenib)

AND

1.4 ONE of the following:

1.4.1 Patient has a contraindication or history of intolerance to ONE of the following regimens:

- Tafinlar (dabrafenib) plus Mekinist (trametinib)
- Zelboraf (vemurafenib) plus Cotellic (cobimetinib)

OR

1.4.2 Provider attests that the patient is not an appropriate candidate for either of the following regimens:

- Tafinlar (dabrafenib) plus Mekinist (trametinib)
- Zelboraf (vemurafenib) plus Cotellic (cobimetinib)

OR

1.4.3 For continuation of prior Mektovi therapy

Product Name: Mektovi	
Diagnosis	Melanoma with NRAS mutation

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of melanoma NRAS-mutated tumor

AND

1.2 Progression after prior immune checkpoint inhibitor therapy

Product Name: Mektovi	
Diagnosis	Melanoma (Melanoma with BRAF mutation, Melanoma with NRAS mutation)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Mektovi therapy

AND

2 - ONE of the following:

2.1 BOTH of the following:

- BRAFV600 mutation positive
- Used in combination with Braftovi (encorafenib)

OR

2.2 NRAS-mutated tumor

Product Name: Mektovi	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Mektovi will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Mektovi	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Mektovi therapy

Prior Authorization Guideline

GL-89693 Mektovi

Formulary

Formulary Note

Guideline Note:

Effective Date:	9/1/2021

1 . Criteria

Product Name: Mektovi	
Diagnosis	Melanoma with BRAF mutation
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 ONE of the following diagnoses:

- Unresectable melanoma
- Metastatic melanoma

AND

1.2 Patient is positive for BRAFV600 mutation

AND

1.3 Used in combination with Braftovi (encorafenib)

AND

1.4 ONE of the following:

1.4.1 Patient has a contraindication or history of intolerance to ONE of the following regimens:

- Tafinlar (dabrafenib) plus Mekinist (trametinib)
- Zelboraf (vemurafenib) plus Cotellic (cobimetinib)

OR

1.4.2 Provider attests that the patient is not an appropriate candidate for either of the following regimens:

- Tafinlar (dabrafenib) plus Mekinist (trametinib)
- Zelboraf (vemurafenib) plus Cotellic (cobimetinib)

OR

1.4.3 For continuation of prior Mektovi therapy

Product Name: Mektovi	
Diagnosis	Melanoma with NRAS mutation

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of melanoma NRAS-mutated tumor

AND

1.2 Progression after prior immune checkpoint inhibitor therapy

Product Name: Mektovi	
Diagnosis	Melanoma (Melanoma with BRAF mutation, Melanoma with NRAS mutation)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Mektovi therapy

AND

2 - Used in combination with Braftovi (encorafenib)

Product Name: Mektovi	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Mektovi will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Mektovi	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Mektovi therapy

2 . Revision History

Date	Notes
7/9/2021	Copied from NY

Prior Authorization Guideline

GL-62896 Mozobil

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Mozobil	
Approval Length	4 Day(s)*
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

- Patients with non-Hodgkin’s lymphoma (NHL) who will be undergoing autologous hematopoietic stem cell (HSC) transplantation

• Patients with multiple myeloma (MM) who will be undergoing autologous HSC transplantation **AND** **2** - Used in combination with granulocyte-colony stimulating factor (G-CSF) [e.g., Zarxio (filgrastim)] **AND** **3** - Prescribed by, or in consultation with, a hematologist/oncologist	
Notes	*Note: Authorization will be issued for 1 course of therapy (up to four days of therapy).

2 . Revision History

Date	Notes
3/11/2020	C&S Implementation

Prior Authorization Guideline

GL-62933 Mulpleta

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Mulpleta	
Diagnosis	Thrombocytopenia
Approval Length	1 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of thrombocytopenia	

AND

2 - Patient has chronic liver disease

AND

3 - Patient is scheduled to undergo a procedure

2 . Revision History

Date	Notes
3/13/2020	C&S 2020 implementations

Prior Authorization Guideline

GL-108461 Myalept

Formulary

Formulary Note

Guideline Note:

Effective Date:	8/1/2022

1 . Criteria

Product Name: Myalept	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of congenital or acquired generalized lipodystrophy associated with leptin deficiency

AND

2 - Used as an adjunct to diet modification

AND

3 - Prescribed by an endocrinologist

AND

4 - Patient has at least ONE of the following:

4.1 Diabetes mellitus or insulin resistance with persistent hyperglycemia (hemoglobin A1C greater than 7.0%) despite BOTH of the following:

- Dietary intervention
- Optimized insulin therapy at maximum tolerated doses

OR

4.2 Persistent hypertriglyceridemia (triglycerides greater than 250 milligrams per deciliter) despite BOTH of the following:

- Dietary intervention
- Optimized therapy with at least two triglyceride-lowering agents from different classes (e.g., fibrates, statins) at maximum tolerated doses

Product Name: Myalept	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Myalept therapy

AND

2 - Used as an adjunct to diet modification

AND

3 - Prescribed by an endocrinologist

Prior Authorization Guideline

GL-62935 Natpara

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Natpara	
Diagnosis	Hypoparathyroidism
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

- Diagnosis of hypocalcemia resulting from chronic hypoparathyroidism

- 25-hydroxy vitamin D level is above the lower limit of the normal laboratory reference range
- Patient is currently on active vitamin D (calcitriol) therapy
- Total serum calcium level (albumin corrected) is above 7.5 milligrams (mg) per deciliter (dL)

AND

2 - ONE of the following

- Patient is currently on calcium supplementation of 1-2 grams per day of elemental calcium in divided doses
- Patient has a contraindication to calcium supplementation

AND

3 - Prescribed by ONE of the following:

- Endocrinologist
- Nephrologist

Product Name: Natpara	
Diagnosis	Hypoparathyroidism
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Total serum calcium level (albumin corrected) within the lower half of the normal range (approximately 8 to 9 milligrams (mg) per deciliter (dL)

AND

2 - Patient continues to take concomitant calcium supplementation that is sufficient to meet daily requirements

AND

3 - Prescribed by ONE of the following:

- Endocrinologist
- Nephrologist

2 . Revision History

Date	Notes
3/13/2020	C&S 2020 implementations

Prior Authorization Guideline

GL-108470 Nerlynx

Formulary

Formulary Note

Guideline Note:

Effective Date:	8/1/2022

1 . Criteria

Product Name: Nerlynx	
Diagnosis	Early-Stage Breast Cancer
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of early-stage breast cancer	

AND

2 - Disease is human epidermal growth factor receptor 2 (HER2)-positive

AND

3 - Patient has received adjuvant trastuzumab-based therapy (e.g., Herceptin, Kanjinti)

AND

4 - Patient will not have more than 12 months of treatment per occurrence*

Notes	*Duration of coverage is limited to 12 months per occurrence.

Product Name: Nerlynx	
Diagnosis	Advanced or Metastatic Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced or metastatic breast cancer

AND

2 - Disease is human epidermal growth factor receptor 2 (HER2)-positive

AND

3 - Patient has received two or more prior anti-HER2 based regimens in metastatic setting

AND

4 - Will be used in combination with capecitabine (generic Xeloda)

Product Name: Nerlynx	
Diagnosis	Breast Cancer with Brain Metastases
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - Patient has brain metastases

AND

3 - Disease is human epidermal growth factor receptor 2 (HER2)-positive

AND

4 - Used in combination with ONE of the following:

- capecitabine (generic Xeloda)
- Paclitaxel

Product Name: Nerlynx	
Diagnosis	Advanced or Metastatic Breast Cancer, Breast Cancer with Brain Metastases

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Nerlynx therapy

Product Name: Nerlynx	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Nerlynx	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Nerlynx therapy

Prior Authorization Guideline

GL-81215 Neupro

Formulary

Formulary Note

Guideline Note:

Effective Date:	4/1/2021

1 . Criteria

Product Name: Neupro	
Diagnosis	Parkinson’s disease*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient has had a therapeutic failure to a 30-day trial of ONE preferred medication

OR

1.2 Patient has allergy to preferred medications

OR

1.3 Patient has a contraindication to or drug interaction with preferred medications

OR

1.4 Patient has a history of unacceptable/toxic side effects to preferred medications

OR

1.5 Patient is unable to swallow (dysphagia)

Notes	*Applies to Central Nervous System (CNS) Agents - Parkinson's Agents. PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Neupro	
Diagnosis	Restless Legs Syndrome*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient has had a therapeutic failure to a 30-day trial of ONE preferred medication

OR

1.2 Patient has allergy to preferred medications **OR** **1.3** Patient has a contraindication to or drug interaction with preferred medications **OR** **1.4** Patient has a history of unacceptable/toxic side effects to preferred medications	
Notes	*Applies to Central Nervous System (CNS) Agents: Restless Legs Syndrome PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html

2 . Revision History

Date	Notes
2/16/2021	New guideline

Prior Authorization Guideline

GL-56582 Nexavar

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2020
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Nexavar	
Diagnosis	Renal Cell Carcinoma (RCC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of renal cell carcinoma (RCC)

AND

2 - ONE of the following:

2.1 Disease has relapsed

OR

2.2 BOTH of the following:

- Medically or surgically unresectable tumor
- Diagnosis of Stage IV disease

Product Name: Nexavar	
Diagnosis	Hepatocellular Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hepatocellular carcinoma

AND

2 - ONE of the following:

2.1 Patient has metastatic disease

OR

2.2 Patient has extensive liver tumor burden

OR

2.3 Patient is inoperable by performance status or comorbidity (local disease or local disease with minimal extrahepatic disease only)

OR

2.4 BOTH of the following:

- Patient is not a transplant candidate
- Disease is unresectable

Product Name: Nexavar	
Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ALL of the following:

1.1.1 Diagnosis of ONE of the following:

- Follicular carcinoma
- Hürthle cell carcinoma
- Papillary carcinoma

AND

1.1.2 ONE of the following:

- Unresectable recurrent disease
- Persistent locoregional disease

- Metastatic disease

AND

1.1.3 ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

AND

1.1.4 Disease is refractory to radioactive iodine treatment

OR

1.2 ALL of the following:

1.2.1 Diagnosis of medullary thyroid carcinoma

AND

1.2.2 ONE of the following:

- Disease is progressive
- Disease is symptomatic with distant metastases

AND

1.2.3 History of failure, contraindication, or intolerance to ONE of the following:

- Caprelsa (vandetanib)
- Cometriq (cabozantinib)

Product Name: Nexavar	
Diagnosis	Soft Tissue Sarcoma

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of angiosarcoma

OR

2 - Diagnosis of desmoid tumors / aggressive fibromatosis

OR

3 - BOTH of the following:

3.1 Diagnosis of progressive gastrointestinal stromal tumors (GIST)

AND

3.2 History of failure, contraindication, or intolerance to ONE of the following:

- Gleevec (imatinib)
- Sutent (sunitinib)
- Stivarga (regorafenib)

OR

4 - Diagnosis of solitary fibrous tumor/hemangiopericytoma

Product Name: Nexavar	
Diagnosis	Bone Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of chordoma

AND

1.2 Disease is recurrent

OR

2 - BOTH of the following:

2.1 ONE of the following:

- Diagnosis of osteosarcoma
- Diagnosis of dedifferentiated chondrosarcoma
- Diagnosis of high-grade undifferentiated pleomorphic sarcoma (UPS)

AND

2.2 Not used as first-line therapy

Product Name: Nexavar	
Diagnosis	Acute Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - Patient has FLT3-ITD mutation-positive disease

AND

3 - ONE of the following:

- Patient has relapsed disease
- Patient has refractory disease

AND

4 - Used in combination with ONE of the following:

- Vidaza (azacitidine)
- Dacogen (decitabine)

AND

5 - Patient is unable to tolerate more aggressive treatment regimens

Product Name: Nexavar	
Diagnosis	Ovarian Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Ovarian cancer
- Fallopian tube cancer

- Primary peritoneal cancer

AND

2 - ONE of the following:

- Patient has persistent disease
- Patient has recurrent disease

AND

3 - Disease is platinum-resistant

AND

4 - Used in combination with topotecan

Product Name: Nexavar	
Diagnosis	Renal Cell Carcinoma (RCC), Hepatocellular Carcinoma, Thyroid Cancer, Soft Tissue Sarcoma, Bone Cancer, Acute Myeloid Leukemia, Ovarian Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Nexavar therapy

Product Name: Nexavar	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Nexavar will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Nexavar	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Nexavar therapy

2 . Revision History

Date	Notes
11/6/2019	New Guideline.

Prior Authorization Guideline

GL-105847 Ninlaro

Formulary

Formulary Note

Guideline Note:

Effective Date:	6/1/2022

1 . Criteria

Product Name: Ninlaro	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of multiple myeloma	

AND

2 - ONE of the following:

2.1 BOTH of the following:

- Patient has received at least one prior therapy for multiple myeloma [e.g., Velcade (bortezomib)]
- Used as part of a combination regimen including dexamethasone [Note: combination regimen may include additional agents, such as Revlimid (lenalidomide)]

OR

2.2 BOTH of the following:

- Used as primary therapy
- Used in combination with dexamethasone and Revlimid (lenalidomide)

OR

2.3 BOTH of the following:

2.3.1 Patient is a transplant candidate

AND

2.3.2 ONE of the following:

2.3.2.1 Patient has symptomatic disease following response to primary myeloma therapy

OR

2.3.2.2 Response or stable disease following autologous stem cell transplant

Product Name: Ninlaro	
Diagnosis	Systemic Light Chain Amyloidosis

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of relapsed or refractory systemic light chain amyloidosis

Product Name: Ninlaro	
Diagnosis	Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Waldenström macroglobulinemia/lymphoplasmacytic lymphoma

AND

2 - Used in combination with rituximab and dexamethasone

Product Name: Ninlaro	
Diagnosis	Multiple Myeloma, Systemic Light Chain Amyloidosis, Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Ninlaro therapy

Product Name: Ninlaro	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Ninlaro	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Ninlaro therapy

Prior Authorization Guideline

GL-62936 Nityr

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Nityr	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of hereditary tyrosinemia type 1	

2 . Revision History

Date	Notes
3/6/2020	C&S 2020 Implementation

Prior Authorization Guideline

GL-81656 Nocdurna

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/1/2021

1 . Criteria

Product Name: Nocdurna	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of nocturia due to nocturnal polyuria (as defined by nighttime urine production that exceeds one-third of the 24-hour urine production)

AND

2 - Patient wakes at least twice per night on a reoccurring basis to void

AND

3 - Documented serum sodium level is currently within normal limits of the normal laboratory reference range and has been within normal limits over the previous six months

AND

4 - The patient has been evaluated for other medical causes and has either not responded to, tolerated, or has a contraindication to treatments for identifiable medical causes [e.g., overactive bladder, benign prostatic hyperplasia/lower urinary tract symptoms (BPH/LUTS), elevated post-void residual urine, and heart failure]

AND

5 - Prescriber attests that the risks have been assessed and benefits outweigh the risks

Product Name: Nocdurna	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Patient has routine monitoring for serum sodium levels

AND

3 - Prescriber attests that the risks of hyponatremia have been assessed and benefits outweigh the risks

Prior Authorization Guideline

GL-106442 Northera

Formulary

Formulary Note

Guideline Note:

Effective Date:	7/1/2022

1 . Criteria

Product Name: Brand Northera, generic droxidopa	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of symptomatic neurogenic orthostatic hypotension (nOH) as defined by ONE of the following when an upright position is assumed or when using a head-up tilt-table testing at an angle of at least 60 degrees:

- At least a 20 millimeters of mercury (mm Hg) fall in systolic pressure

- At least a 10 mm Hg fall in diastolic pressure

AND

2 - nOH caused by ONE of the following:

- Primary autonomic failure (e.g., Parkinson's disease, multiple system atrophy, and pure autonomic failure)
- Dopamine beta-hydroxylase deficiency
- Non-diabetic autonomic neuropathy

AND

3 - Diagnostic evaluation has excluded other causes associated with orthostatic hypotension (e.g., congestive heart failure, fluid restriction, malignancy)

AND

4 - The patient has tried at least TWO of the following non-pharmacologic interventions:

- Discontinuation of drugs which can cause orthostatic hypotension [e.g., diuretics, antihypertensive medications (primarily sympathetic blockers), anti-anginal drugs (nitrates), alpha-adrenergic antagonists, and antidepressants]
- Raising the head of the bed 10 to 20 degrees
- Compression garments to the lower extremities or abdomen
- Physical maneuvers to improve venous return (e.g., regular modest-intensity exercise)
- Increased salt and water intake, if appropriate
- Avoiding precipitating factors (e.g., overexertion in hot weather, arising too quickly from supine to sitting or standing)

AND

5 - No previous diagnosis of supine hypertension

AND

6 - Prescribed by or in consultation with ONE of the following specialists:

- Cardiologist

- Neurologist
- Nephrologist

AND

7 - ONE of the following:

7.1 Failure (after a trial of at least 30 days) of BOTH of the following confirmed by claims history or submitted medical records:

- fludrocortisone (generic Florinef)
- midodrine (generic ProAmatine)

OR

7.2 History of contraindication or intolerance to BOTH of the following:

- fludrocortisone (generic Florinef)
- midodrine (generic ProAmatine)

Product Name: Brand Northera, generic droxidopa	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to the requested therapy

AND

2 - Physiological countermeasures for neurogenic orthostatic hypotension (nOH) continue to be employed

Prior Authorization Guideline

GL-56579 Nubeqa

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2020
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Nubeqa	
Diagnosis	Prostate cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of prostate cancer

AND

2 - Disease is castration-resistant or recurrent

AND

3 - Disease is non-metastatic

AND

4 - ONE of the following:

4.1 Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g. Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

OR

4.2 Patient has had bilateral orchiectomy

Product Name: Nubeqa	
Diagnosis	Prostate cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Nubeqa therapy

Product Name: Nubeqa	
Diagnosis	NCCN Recommended Regimens

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Nubeqa will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Nubeqa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Nubeqa therapy

2 . Revision History

Date	Notes
11/6/2019	New Guideline.

Prior Authorization Guideline

GL-62939 Nuedexta

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Nuedexta	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of pseudobulbar affect (PBA)	

2 . Revision History

Date	Notes
3/6/2020	C&S Implementation

Prior Authorization Guideline

GL-109295 Ocaliva

Formulary

Formulary Note

Guideline Note:

Effective Date:	9/1/2022

1 . Criteria

Product Name: Ocaliva	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary biliary cholangitis

AND

2 - ONE of the following:

2.1 Patient does not have cirrhosis

OR

2.2 Patient has compensated cirrhosis without evidence of portal hypertension

AND

3 - ONE of the following:

3.1 BOTH of the following:

3.1.1 Used in combination with ursodeoxycholic acid (e.g., Urso, ursodiol)

AND

3.1.2 Patient has failed to achieve an alkaline phosphatase (ALP) level of less than 1.67 times the upper limit of normal after at least 12 consecutive months of treatment with ursodeoxycholic acid (e.g., Urso, ursodiol)

OR

3.2 History of contraindication or intolerance to ursodeoxycholic acid (e.g., Urso, ursodiol) (please specify contraindication or intolerance)

AND

4 - Prescribed by ONE of the following:

- Hepatologist
- Gastroenterologist

Product Name: Ocaliva	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., laboratory values) documenting a reduction in alkaline phosphatase (ALP) level from pre-treatment baseline (i.e., prior to Ocaliva therapy) while on Ocaliva therapy

AND

2 - ONE of the following:

2.1 Patient does not have cirrhosis

OR

2.2 Patient has compensated cirrhosis without evidence of portal hypertension

AND

3 - Prescribed by ONE of the following:

- Hepatologist
- Gastroenterologist

2 . Revision History

Date	Notes

7/12/2022	Changed clinical criteria based on changes to prescribing information . Revised order of listing of two criteria to better align with prescribing information.

Prior Authorization Guideline

GL-96751 Odomzo

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: Odomzo	
Diagnosis	Basal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic basal cell carcinoma (BCC)

OR

2 - Diagnosis of diffuse basal cell carcinoma (BCC) formation (e.g., Gorlin syndrome, other genetic forms of multiple BCC)

OR

3 - Both of the following:

3.1 Diagnosis of locally advanced basal cell carcinoma

AND

3.2 ONE of the following:

- Cancer has recurred following surgery
- Cancer has recurred following radiation
- Patient is not a candidate for surgery
- Patient is not a candidate for radiation

Product Name: Odomzo	
Diagnosis	Basal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Odomzo therapy.

Product Name: Odomzo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Odomzo will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Odomzo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Odomzo therapy

2 . Revision History

Date	Notes
10/15/2021	Update

Prior Authorization Guideline

GL-56811 Omnipod

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2020

Note:

NOTE: This guideline DOES NOT apply to V-GO products (NDC's 08560-9400-01, 08560-9400-02 or 08560-9400-03)

1 . Criteria

Product Name: Omnipod	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - The patient must have completed a comprehensive diabetes education program within the previous 12 months

AND

2 - The patient is adherent to the insulin therapy recommended by an endocrinologist as demonstrated by monitoring logs and claims history maintained for at least 3 months

AND

3 - A letter or documentation indicating the patient regularly works with a certified diabetes educator

AND

4 - Insulin injections are required greater than or equal to 3 times a day

AND

5 - Self-Home glucose monitoring is required greater than or equal to 4 times a day

AND

6 - The patient meets ONE of the following:

- HgA1C greater than 7%
- History of recurrent hypoglycemia
- Wide fluctuations in blood glucose before mealtime
- A marked early morning increase in fasting blood sugar (dawn phenomenon- glucose level exceeds 200 milligram (mg) per deciliter (dL))
- History of ketoacidosis
- A history of severe glycemic excursions

AND

7 - The individual (or someone assisting the individual) is capable of managing the pump and that the desired improvement in metabolic control can be achieved

Product Name: Omnipod	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescriber must attest to BOTH of the following:

1.1 The individual (or someone assisting the individual) is able to manage the pump

AND

1.2 There is objective documented evidence of improvement in control of diabetes (specific to baseline status of disease for individual patients)

2 . Revision History

Date	Notes
11/12/2019	C&S Implementation

Prior Authorization Guideline

GL-79901 Onureg

Formulary

Formulary Note

Guideline Note:

Effective Date:	3/1/2021

1 . Criteria

Product Name: Onureg	
Diagnosis	Acute Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Acute Myeloid Leukemia	

AND

2 - Achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy

AND

3 - Patient is not able to complete intensive curative therapy (e.g., transplant-ineligible)

Product Name: Onureg	
Diagnosis	Acute Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Onureg therapy

Product Name: Onureg	
Diagnosis	NCCN Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - The use of Onureg is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Onureg	
Diagnosis	NCCN Regimens

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - There is documentation of positive clinical response to Onureg therapy

2 . Revision History

Date	Notes
1/21/2021	Copy of NY gl-79800 New Implementations

Prior Authorization Guideline

GL-77282 Ophthalmic Agents - Antibiotic and Antibiotic-Steroid Combination Drops and Ointments

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2021

1 . Criteria

Product Name: Azasite opth soln, Klarity-A opth soln, generic bacitracin opth ointment, generic gentamicin opth ointment, generic sulfacetamide opth ointment, Brand Blephamide opth susp, generic prednisolone/sulfacetamide opth susp, Brand Blephamide opth ointment, generic neomycin/polymyxin/ hydrocortisone drops, Pred-G opth susp, Pred-G opth ointment, Tobradex ST, Brand Tobradex, generic tobramycin/dexamethasone opth susp, Zylet opth susp	
Approval Length	14 Day(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Patient had an inadequate clinical response to a three day trial each of TWO preferred medications**

OR

2 - Patient cannot be changed to a preferred medication due to ONE of the following:

2.1 Patient has an allergy to preferred medications

OR

2.2 Patient has a contraindication to, or drug interaction with, preferred medications

OR

2.3 Patient has a history of unacceptable/toxic side effects to preferred medications

OR

3 - The infection is caused by an organism resistant to preferred medications (NOTE: Include the diagnosis and any culture and sensitivity reports)

Notes	**NOTE PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Besivance opth susp, Brand Zymaxid opth soln, generic gatifloxacin opth soln, generic levofloxacin opth soln, Moxeza opth soln	
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient had an inadequate clinical response to a three day trial each of TWO preferred medications**

OR **2** - Patient cannot be changed to a preferred medication due to ONE of the following: **2.1** Patient has an allergy to preferred medications **OR** **2.2** Patient has a contraindication to, or drug interaction with, preferred medications **OR** **2.3** Patient has a history of unacceptable/toxic side effects to preferred medications **OR** **3** - The infection is caused by an organism resistant to preferred medications (NOTE: Include the diagnosis and any culture and sensitivity reports)

Notes	**NOTE PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
11/22/2020	Removed Neomycin/Polymyxin/Bacitracin/Hydrocortisone oint

Prior Authorization Guideline

GL-105361 Ophthalmic Agents - Glaucoma Agents

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/1/2022

1 . Criteria

Product Name: Alphagan P 0.1%, Brand Azopt, Combigan, Brand Travatan Z	
Approval Length	12 month(s)
Guideline Type	Step Therapy, Prior Authorization
Approval Criteria **1** - Patient had an inadequate clinical response to a trial of no less than 30 days of at least ONE preferred* product	
Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: apraclonidine, Betoptic-S, bimatoprost ophth soln, generic brimonidine 0.15%, generic brinzolamide, Iopidine, Brand Istalol, Lumigan, generic travoprost, Vyzulta, Xelpros, Zioptan, Brand Trusopt, Brand Cosopt, Brand Cosopt PF, Brand Xalatan, Brand Timoptic, Brand Timoptic-XE	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient had an inadequate clinical response to a trial of no less than 30 days each of at least TWO preferred or step therapy products*

OR

2 - Patient cannot be changed to a preferred* medication due to ONE of the following:

- Allergy to preferred medications
- Contraindications to or drug interaction with preferred medications
- History of unacceptable/toxic side effects to preferred medications

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
3/29/2022	Added Prior Authorization to guideline type section

Prior Authorization Guideline

GL-77534 Ophthalmic Agents, Ophthalmic Steroids

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2021

1 . Criteria

Product Name: Alrex, Flarex, Inveltys, brand Lotemax, generic loteprednol etabonate, Lotemax SM, Maxidex	
Approval Length	30 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient has had an inadequate clinical response to a 14 day trial of TWO preferred medications

OR **1.2** Patient cannot be changed to a preferred medication due to ONE of the following*: • Patient has an allergy to preferred medications • Patient has a contraindication to, or drug interaction with, preferred medications • Patient has a history of unacceptable/toxic side effects to preferred medications

Notes	Ohio PDL: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
11/25/2020	2021 Implementation

Prior Authorization Guideline

GL-77283 Ophthalmic Agents- Antihistamines and Mast Cell Stabilizers

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2021

1 . Criteria

Product Name: Alocril, Alomide. Bepreve, generic epinastine, Lastacaft, Pazeo, Zerviate	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient had a therapeutic failure to a 14 day trial of ONE of the preferred agents*

OR

2 - Patient cannot be changed to a preferred medication due to ONE of the following: **2.1** Patient has an allergy to preferred medications **OR** **2.2** Patient has a contraindication to, or drug interaction with, preferred medications **OR** **2.3** Patient has a history of unacceptable/toxic side effects to preferred medications	
Notes	*NOTE PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
11/30/2020	Added Pazeo and Zerviate

Prior Authorization Guideline

GL-107352 Ophthalmic Agents: Dry Eye Treatments

Formulary

Formulary Note

Guideline Note:

Effective Date:	7/1/2022

1 . Criteria

Product Name: Brand Restasis Trays	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria **1** - Patient must have a claim for an artificial tear or over-the-counter (OTC) dry eye drop in the past 120 days*	
Notes	*RxClaims should be validated

Product Name: Restasis Multidose, Cequa, Xiidra, Eysuvis, Tyrvaya, Generic cyclosporine (ophth)	
Approval Length	Eysuvis is 14 days; all others are 12 months
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient must have a claim for an artificial tear or over-the-counter (OTC) dry eye drop in the past 120 days*

AND

2 - ONE of the following:

2.1 Patient has ONE of the following:

- Patient has allergy to preferred medications
- Patient has a contraindication or drug-to-drug interaction with preferred medications
- Patient has a history of unacceptable/toxic side effects to preferred medications

OR

2.2 Patient has had a therapeutic failure to 30 days of one of the preferred medications**

Notes	*RxClaims should be validated **PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
5/19/2022	Added Tyrvaya, Generic cyclosporine.

Prior Authorization Guideline

GL-56807 Ophthalmic Agents: NSAIDs

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2020

1 . Criteria

Product Name: Acuvail, bromfenac 0.09%, Bromsite, Ilevro, Nevanac, Prolensa	
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient cannot be changed to a preferred medication* due to ONE of the following:

1.1.1 Patient has allergy to preferred medications

OR **1.1.2** Patient has a contraindication or drug-to-drug interaction with preferred medications **OR** **1.1.3** Patient has a history of unacceptable/toxic side effects to preferred medications **OR** **1.2** BOTH of the following: **1.2.1** Patient has had a therapeutic failure to a 3 day trial of one preferred medication **AND** **1.2.2** If applicable, the requested medication's corresponding generic has been attempted and failed, or is contraindicated

Notes	*NOTE: PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
11/12/2019	C&S Implementation

Prior Authorization Guideline

GL-107346 Orfadin

Formulary

Formulary Note

Guideline Note:

Effective Date:	8/1/2022

1 . Criteria

Product Name: Brand Orfadin, generic nitisinone	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of hereditary tyrosinemia type 1	

AND

2 - Special clinical circumstances exist that precludes the use of Nityr (nitisinone) tablets for the patient (document special clinical circumstance)

Product Name: Brand Orfadin, generic nitisinone	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient shows evidence of positive clinical response (e.g., decrease in urinary/plasma succinylacetone and alpha-1-microglobulin levels) while on Orfadin therapy

Prior Authorization Guideline

GL-81621 Orgovyx

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/1/2021

1 . Criteria

Product Name: Orgovyx	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of advanced prostate cancer	

AND

2 - Patient is a candidate for at least one year of continuous androgen-deprivation therapy

AND

3 - ONE of the following:

- Evidence of biochemical [PSA (prostate-specific antigen)] or clinical relapse after local primary intervention with curative intent
- Newly diagnosed hormone-sensitive metastatic disease
- Advanced localized disease unlikely to be cured by local primary intervention with curative intent

AND

4 - Patient has been without any major adverse cardiovascular events within 6 months before initiation (e.g., myocardial infarction, stroke)

Product Name: Orgovyx	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Orgovyx	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Orgovyx	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Orgovyx therapy

Prior Authorization Guideline

GL-99055 Otic Agents- Antibacterial and Antibacterial-Steroid Combinations

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: Brand Cetraxal, generic ciprofloxacin otic soln, generic ciprofloxacin/dexamethasone otic susp, Brand Otovel, generic ciprofloxacin/fluocinolone otic soln	
Approval Length	14 Day(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Both of the following: **1.1** Patient has had a therapeutic failure to a 7day trial of ONE preferred medication	

AND

1.2 The requested medication's corresponding generic (if covered by the state) has been attempted and failed or is contraindicated

OR

2 - Patient cannot be changed to a preferred medication due to ONE of the following:

- Patient has an allergy to preferred medications
- Patient has a contraindication to, or drug interaction with, preferred medications
- Patient has a history of unacceptable/toxic side effects to preferred medications

OR

3 - The infection is caused by an organism resistant to preferred medications (Note: Include the diagnosis and any culture and sensitivity reports)

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
12/1/2021	Updated

Prior Authorization Guideline

GL-105198 Oxbryta

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/1/2022

1 . Criteria

Product Name: Oxbryta tablet, Oxbryta tablet for suspension	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of sickle cell disease	

AND

2 - Patient is greater than or equal to 4 years of age

AND

3 - One of the following:

3.1 Patient is currently receiving hydroxyurea therapy

OR

3.2 Patient has a history of treatment failure, intolerance, or contraindication to hydroxyurea therapy

AND

4 - Patient has previously experienced 1 or more sickle cell-related vaso-occlusive crises within the previous 12 months

AND

5 - Baseline hemoglobin is less than or equal to 10.5 g/dL (grams per deciliter)

AND

6 - Patient is not receiving concomitant chronic, prophylactic blood transfusion therapy

AND

7 - Patient is not to receive Oxbryta in combination with Adakveo (crizanlizumab-tmca)

AND

8 - Prescribed by, or in consultation with, a hematologist or other specialist with expertise in the diagnosis and management of sickle cell disease

Product Name: Oxbryta tablet, Oxbryta tablet for suspension	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Oxbryta therapy as demonstrated by at least ONE of the following:

1.1 Increase in hemoglobin by greater than or equal to 1 g/dL (gram per deciliter) from baseline

OR

1.2 Decrease in indirect bilirubin from baseline

OR

1.3 Decrease in percent reticulocyte count from baseline

OR

1.4 Patient has experienced a reduction in sickle cell-related vaso-occlusive crises

AND

2 - Patient is not receiving Oxbryta in combination with Adakveo (crizanlizumab-tmca)

AND

3 - Patient is not receiving concomitant chronic, prophylactic blood transfusion therapy

AND

4 - Prescribed by, or in consultation with a hematologist, or other specialist with expertise in the diagnosis and management of sickle cell disease

2 . Revision History

Date	Notes
3/25/2022	Copy NY

Prior Authorization Guideline

GL-95269 Palforzia

Formulary

Formulary Note

Guideline Note:

Effective Date:	10/1/2021

1 . Criteria

Product Name: Palforzia	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis and clinical history of peanut allergy as documented by BOTH of the following:

1.1 A serum peanut-specific IgE level of greater than or equal to 0.35 kUA/L (kilo units of allergen per liter)

AND

1.2 A mean wheal diameter that is at least 3mm (millimeters) larger than the negative control on skin-prick testing for peanut

AND

2 - ONE of the following:

2.1 BOTH of the following:

- Patient is 4 to 17 years of age
- Patient is in the initial dose escalation phase of therapy

OR

2.2 BOTH of the following:

- Patient is 4 years of age and older
- Patient is in the up-dosing or maintenance phase of therapy

AND

3 - Used in conjunction with a peanut-avoidant diet

AND

4 - Patient does not have one of the following:

- History of eosinophilic esophagitis (EoE) or eosinophilic gastrointestinal disease
- History of severe or life-threatening episode(s) of anaphylaxis or anaphylactic shock within the past 2 months
- Severe or poorly controlled asthma

AND

5 - Prescribed by or in consultation with an allergist or immunologist

AND

6 - Prescriber is certified/enrolled in the Palforzia REMS (Risk Evaluation and Mitigation Strategy) Program

Product Name: Palforzia	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Palforzia therapy

AND

2 - Used in conjunction with a peanut-avoidant diet

AND

3 - Prescribed by or in consultation with an allergist or immunologist

AND

4 - Prescriber is certified/enrolled in the Palforzia REMS (Risk Evaluation and Mitigation Strategy) Program

2 . Revision History

Date	Notes

9/30/2021	Corrected “meal” to “mean” typo at step 1.2 of initial auth.

Prior Authorization Guideline

GL-90251 Palynziq

Formulary

Formulary Note

Guideline Note:

Effective Date:	10/1/2021

1 . Criteria

Product Name: Palynziq	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of phenylketonuria (PKU)	

AND

2 - Patient is actively on a phenylalanine-restricted diet

AND

3 - ONE of the following:

3.1 Patient has a contraindication to saptropterin (list reason)

OR

3.2 History of failure or intolerance to sapropterin therapy (document date of trial and list reason for therapeutic failure or intolerance) as determined by a one- to four-week trial of sapropterin

AND

4 - Physician attestation that the patient will not be receiving Palynziq in combination with sapropterin dihydrochloride

AND

5 - Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient has a blood phenylalanine concentration greater than 600 micromoles/liter

Product Name: Palynziq	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is actively on a phenylalanine-restricted diet

AND

2 - ONE of the following:

2.1 Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient has a blood phenylalanine concentration less than 600 micromoles/liter

OR

2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient has achieved a 20% reduction in blood phenylalanine concentration from pre-treatment baseline

OR

2.3 Patient is in initial titration/maintenance phase of dosing regimen and dose is being titrated based on blood phenylalanine concentration response up to maximum labeled dosage of 60 milligrams once daily

AND

3 - Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient is not receiving Palynziq in combination with sapropterin dihydrochloride [Prescription claim history that does not show any concomitant sapropterin dihydrochloride claim within 60 days of reauthorization request may be used as documentation]

Prior Authorization Guideline

GL-56514 Panretin

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2020
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Panretin	
Diagnosis	AIDS-related Kaposi's Sarcoma (KS)
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of acquired immunodeficiency syndrome (AIDS)-related Kaposi's Sarcoma (KS)	

AND

2 - Patient is not receiving systemic anti-KS treatment

Product Name: Panretin	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Panretin will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Panretin	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Panretin therapy

2 . Revision History

Date	Notes
11/5/2019	New Guideline.

Prior Authorization Guideline

GL-89153 Pemazyre

Formulary

Formulary Note

Guideline Note:

Effective Date:	9/1/2021

1 . Criteria

Product Name: Pemazyre	
Diagnosis	Cholangiocarcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cholangiocarcinoma

AND

2 - Disease is ONE of the following:

- Unresectable locally advanced
- Metastatic

AND

3 - Disease has presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement

AND

4 - Patient has been previously treated

Product Name: Pemazyre	
Diagnosis	Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of myeloid/lymphoid/mixed lineage neoplasms with eosinophilia

AND

2 - Disease has presence of a fibroblast growth factor receptor 1 (FGFR1) rearrangement

Product Name: Pemazyre	
Diagnosis	Cholangiocarcinoma, Myeloid/Lymphoid Neoplasms

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Pemazyre therapy

Product Name: Pemazyre	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Pemazyre will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Pemazyre	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Pemazyre therapy

2 . Revision History

Date	Notes

6/30/2021	Copied from NY. Addition of coverage criteria for myeloid/lymphoid n eoplasms according to NCCN

Prior Authorization Guideline

GL-108513 Phexxi

Formulary

Formulary Note

Guideline Note:

Effective Date:	8/1/2022

1 . Criteria

Product Name: Phexxi	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Used for the prevention of pregnancy

AND

2 - ONE of the following:

2.1 Failure to ALL of the following other methods of contraception as confirmed by claims history or submission of medical records:

- Injection (e.g., Depo-Provera)
- Oral Contraceptive [e.g., norethindrone (generic Micronor), Yaz]
- Transdermal Patch (e.g., Twirla, Xulane)
- Vaginal Contraceptive Ring (e.g., Annovera, NuvaRing)
- Diaphragm
- Cervical Cap (e.g., FemCap)
- Female Condom

OR

2.2 History of intolerance or contraindication to ALL of the following methods of contraception (please document intolerance or contraindication):

- Injection (e.g., Depo-Provera)
- Oral Contraceptive [e.g., norethindrone (generic Micronor), Yaz]
- Transdermal Patch (e.g., Twirla, Xulane)
- Vaginal Contraceptive Ring (e.g., Annovera, NuvaRing)
- Diaphragm
- Cervical Cap (e.g., FemCap)
- Female Condom

AND

3 - ONE of the following:

3.1 Failure to nonoxynol-9 based spermicide as confirmed by claims history or submission of medical records

OR

3.2 History of intolerance or contraindication to nonoxynol-9 based spermicide (please document intolerance or contraindication)

AND

4 - Provider attests they have counseled the patient regarding higher rate of pregnancy prevention with the use of other methods of contraception (e.g., injection, oral contraception, transdermal patch, vaginal ring) compared to Phexxi

Prior Authorization Guideline

GL-73355 Piqray

Formulary

Formulary Note

Guideline Note:

Effective Date:	11/1/2020

1 . Criteria

Product Name: Piqray	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of breast cancer	

AND

2 - ONE of the following:

- Advanced
- Metastatic

AND

3 - Disease is hormone receptor (HR)-positive

AND

4 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

5 - Presence of one or more PIK3CA mutations

AND

6 - Patient is ONE of the following:

- Postmenopausal
- Male

AND

7 - Used in combination with fulvestrant

AND

8 - Disease has progressed on or after an endocrine-based regimen

Product Name: Piqray	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Piqray therapy

Product Name: Piqray	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Piqray will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Piqray	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Piqray therapy

2 . Revision History

Date	Notes
9/15/2020	Removed requirement of FDA test confirming PIK3CA mutations

Prior Authorization Guideline

GL-108537 Pomalyst

Formulary

Formulary Note

Guideline Note:

Effective Date:	8/1/2022

1 . Criteria

Product Name: Pomalyst	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple myeloma

AND

2 - ONE of the following:

2.1 Failure of BOTH of the following, confirmed by claims history or submitted medical records:

- Immunomodulatory agent [e.g., Revlimid (lenalidomide)]
- Proteasome inhibitor [e.g., Velcade (bortezomib)]

OR

2.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- Immunomodulatory agent [e.g., Revlimid (lenalidomide)]
- Proteasome inhibitor [e.g., Velcade (bortezomib)]

Product Name: Pomalyst	
Diagnosis	Systemic Light Chain Amyloidosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of systemic light chain amyloidosis

AND

2 - Used in combination with dexamethasone

Product Name: Pomalyst	
Diagnosis	Kaposi Sarcoma

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HIV (human immunodeficiency virus)-negative Kaposi Sarcoma

OR

2 - ALL of the following:

2.1 Diagnosis of AIDS (acquired immunodeficiency syndrome)-related Kaposi Sarcoma

AND

2.2 Patient is currently being treated with antiretroviral therapy (ART), confirmed by claims history or submitted medical records

AND

2.3 NOT used as first-line therapy

Product Name: Pomalyst	
Diagnosis	Primary CNS Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary central nervous system (CNS) lymphoma

AND

2 - Used as second-line or subsequent therapy

Product Name: Pomalyst	
Diagnosis	Multiple Myeloma, Systemic Light Chain Amyloidosis, Kaposi Sarcoma, Primary CNS Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Pomalyst therapy

Product Name: Pomalyst	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Pomalyst	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Pomalyst therapy

Prior Authorization Guideline

GL-66097 Pretomanid

Formulary

Formulary Note

Guideline Note:

Effective Date:	7/1/2020

1 . Criteria

Product Name: Pretomanid	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of pulmonary extensively drug resistant (XDR) tuberculosis (TB)

OR

1.2 Treatment-intolerant or nonresponsive multidrug-resistant (MDR) tuberculosis (TB)

AND

2 - Pretomanid will be used in combination with bedaquiline and linezolid

2 . Revision History

Date	Notes
5/12/2020	New program

Prior Authorization Guideline

GL-104014 Prevymis

Formulary

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Prevymis tablet	
Approval Length	100 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is a recipient of an allogeneic hematopoietic stem cell transplant

AND

2 - Patient is cytomegalovirus (CMV)-seropositive

AND

3 - Provider attests that Prevymis will be initiated between Day 0 and Day 28 post-transplantation (before or after engraftment) and is being prescribed as prophylaxis and not treatment of CMV infection

AND

4 - Documentation of the transplant date, confirming that the request is for 100 days or less post-transplantation

2 . Revision History

Date	Notes
2/23/2022	Removed reauthorization section and added therapy limit language t o align with FDA indication

Prior Authorization Guideline

GL-109263 Procysbi

Formulary

Formulary Note

Guideline Note:

Effective Date:	9/1/2022

1 . Criteria

Product Name: Procysbi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of nephropathic cystinosis	

AND

2 - Patient is 1 year of age or older

AND

3 - ONE of the following:

3.1 Failure to immediate-release cysteamine bitartrate (generic Cystagon), as confirmed by claims history or submission of medical records

OR

3.2 History of intolerance or contraindication to immediate-release cysteamine bitartrate (generic Cystagon) (please specify intolerance or contraindication)

Notes	* UnitedHealthcare generally does not consider frequency of dosing a nd/or lack of compliance to dosing regimens, an indication of medical necessity.

Product Name: Procysbi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Procysbi therapy

Prior Authorization Guideline

GL-78195 Promacta

Formulary

Formulary Note

Guideline Note:

Effective Date:	2/1/2021

1 . Criteria

Product Name: Promacta	
Diagnosis	Chronic Immune Thrombocytopenia (ITP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chronic idiopathic thrombocytopenic purpura (ITP)	

AND

2 - History of failure, contraindication, or intolerance to at least ONE of the following:

- Corticosteroids
- Immunoglobulins
- Splenectomy

Product Name: Promacta	
Diagnosis	Chronic Immune Thrombocytopenia (ITP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Promacta therapy

Product Name: Promacta	
Diagnosis	Chronic Hepatitis C-Associated Thrombocytopenia
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C-associated thrombocytopenia

AND

2 - ONE of the following:

- Planning to initiate and maintain interferon-based treatment

- Currently receiving interferon-based treatment

Product Name: Promacta	
Diagnosis	Chronic Hepatitis C-Associated Thrombocytopenia
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Promacta therapy

AND

2 - Patient is currently on antiviral interferon therapy for treatment of chronic hepatitis C

Product Name: Promacta	
Diagnosis	Aplastic Anemia
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe aplastic anemia

AND

2 - ONE of the following:

2.1 Used in combination with standard immunosuppressive therapy [e.g., Atgam [antithymocyte globulin equine], Thymoglobulin [antithymocyte globulin rabbit], cyclosporine]

OR

2.2 History of failure, contraindication, or intolerance to at least one course of immunosuppressive therapy [e.g., Atgam (antithymocyte globulin equine), Thymoglobulin (antithymocyte globulin rabbit), cyclosporine]

Product Name: Promacta	
Diagnosis	Aplastic Anemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Promacta therapy

2 . Revision History

Date	Notes
12/14/2020	Added Promacta 25mg susp

Prior Authorization Guideline

GL-57539 Pulmozyme

Formulary

Formulary Note

Guideline Note:

Effective Date:	2/1/2020

1 . Criteria

Product Name: Pulmozyme	
Diagnosis	Cystic Fibrosis
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Cystic Fibrosis	

2 . Revision History

Date	Notes
12/4/2019	C&S Implementation

Prior Authorization Guideline

GL-108863 Pyrukynd

Formulary

Formulary Note

Guideline Note:

Effective Date:	8/1/2022

1 . Criteria

Product Name: Pyrukynd	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pyruvate kinase (PK) deficiency based on ALL of the following:

- Presence of at least 2 variant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene, of which at least 1 is a missense variant
- Patient is not homozygous for the c.1436G>A (p.R479H) variant

- Patient does not have 2 non-missense variants (without the presence of another missense variant) in the PKLR gene

AND

2 - Used for the treatment of hemolytic anemia

AND

3 - ONE of the following:

3.1 BOTH of the following:

3.1.1 Baseline hemoglobin less than or equal to 10 grams per deciliter (g/dL)

AND

3.1.2 Patient has had no more than 4 transfusions in the previous 52 weeks and no transfusions in the preceding 3-month period

OR

3.2 Patient has had a minimum of 6 transfusion episodes in the preceding 52 weeks

AND

4 - Prescribed by a nephrologist or hematologist

Product Name: Pyrukynd	
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following*:

1.1.1 Documentation of positive clinical response to Pyrukynd therapy based on ONE of the following:

1.1.1.1 A greater than or equal to 1.5 grams per deciliter (g/dL) increase in hemoglobin from baseline sustained at 2 or more scheduled assessments 4 weeks apart during the initial 24 week period without any transfusions

OR

1.1.1.2 Reduction in transfusions of greater than or equal to 33% in the number of red blood cell units transfused during the initial 24 week period compared with the patient's historical transfusion burden

OR

1.1.1.3 Patient has been on Pyrukynd for greater than 52 weeks and has maintained a positive clinical response to therapy

AND

1.1.2 Prescribed by, or in consultation with, a nephrologist or hematologist

OR

1.2 Documentation does not provide evidence of positive clinical response to Pyrukynd therapy, allow for dose titration with discontinuation of therapy**

Notes	*If criteria met under step 1.1, authorization length is 12 months. **If cr iteria met under step 1.2, authorization length in 4 weeks.

2 . Revision History

Date	Notes
6/30/2022	New guideline

Prior Authorization Guideline

GL-105440 Qinlock

Formulary

Formulary Note

Guideline Note:

Effective Date:	3/30/2022

1 . Criteria

Product Name: Qinlock	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of gastrointestinal stromal tumor (GIST)	

AND

2 - Disease is ONE of the following:

- Advanced
- Unresectable
- Recurrent
- Metastatic

AND

3 - History of failure to ALL of the following:

- imatinib (Gleevec)
- sunitinib (Sutent)
- regorafenib (Stivarga)

Product Name: Qinlock	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Qinlock therapy

Product Name: Qinlock	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Qinlock	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Qinlock therapy	

2 . Revision History

Date	Notes
3/30/2022	Updated GPI

Prior Authorization Guideline

GL-62944 Ravicti

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Ravicti	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of urea cycle disorders (UCDs)

AND

2 - Inadequate response to ONE of the following:

- Dietary protein restriction
- Amino acid supplementation

AND

3 - Will be used concomitantly with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements)

AND

4 - History of failure, contraindication, or intolerance to sodium phenylbutyrate [Buphenyl] *

Notes	*Note: UnitedHealthcare generally does not consider frequency of dos ing and or lack of compliance to dosing regimens an indication of med ical necessity

Product Name: Ravicti	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Ravicti therapy

AND

2 - Patient is actively on dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements)

2 . Revision History

Date	Notes
3/9/2020	C&S 2020 Implementation

Prior Authorization Guideline

GL-74792 Rayos

Formulary

Formulary Note

Guideline Note:

Effective Date:	12/1/2020

1 . Criteria

Product Name: Rayos	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 The requested drug must be used for a Food and Drug Administration (FDA)-approved indication

OR

1.2 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

AND

2 - The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plan's program

AND

3 - Submission of medical records (e.g. chart notes, laboratory values) documenting an intolerance to generic prednisone tablets which is unable to be resolved with attempts to minimize the adverse effects where appropriate

AND

4 - History of failure, contraindication, or intolerance to TWO of the following:

- Dexamethasone tablet, oral solution
- Hydrocortisone tablet
- Methylprednisolone tablet
- Prednisolone tablet, oral solution

Prior Authorization Guideline

GL-57542 Rectiv

Formulary

Formulary Note

Guideline Note:

Effective Date:	2/1/2020

1 . Criteria

Product Name: Rectiv	
Diagnosis	Pain Associated with Chronic Anal Fissures
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of moderate to severe pain associated with chronic anal fissures	

2 . Revision History

Date	Notes
12/4/2019	C&S Implementation

Prior Authorization Guideline

GL-56520 Regranex

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2020
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Regranex	
Approval Length	6 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has a lower extremity diabetic neuropathic ulcer	

2 . Revision History

Date	Notes
11/5/2019	New Guideline.

Prior Authorization Guideline

GL-108869 Repository Corticotropins

Formulary

Formulary Note

Guideline Note:

Effective Date:	8/1/2022

1 . Criteria

Product Name: Acthar, Cortrophin	
Diagnosis	Infantile spasm (i.e., West Syndrome)*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of infantile spasms (i.e., West Syndrome)*

AND

2 - Patient is less than 2 years old

AND

3 - Both of following:

3.1 Initial dose: 75 U/m^2 (units/square meters) intramuscular (IM) twice daily for 2 weeks

AND

3.2 After 2 weeks, dose should be tapered according to the following schedule: 30 U/m^2 IM in the morning for 3 days; 15 U/m^2 IM in the morning for 3 days; 10 U/m^2 IM in the morning for 3 days; 10 U/m^2 IM every other morning for 6 days (3 doses)

Notes	*Acthar gel and Cortrophin gel are not medically necessary for treatment of acute exacerbations of multiple sclerosis. See Background for more information.

Product Name: Acthar, Cortrophin	
Diagnosis	Opsoclonus-myoclonus syndrome (i.e., OMS, Kinsbourne Syndrome)*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of opsoclonus-myoclonus syndrome (i.e., OMS, Kinsbourne Syndrome)*

AND

2 - If the request is for Acthar gel, provider submits documentation of reason or special circumstance patient cannot use Cortrophin Gel

Notes	*Acthar gel and Cortrophin gel are not medically necessary for treatm ent of acute exacerbations of multiple sclerosis. See Background for more information.

2 . Background

Benefit/Coverage/Program Information
Acthar Gel and Purified Cortrophin Gel are unproven and not medically necessary for treatment of the following disorders and diseases: 1. Allergic States: Serum sickness 2. Collagen Diseases: systemic lupus erythematosus, systemic dermatomyositis (polymyositis) 3. Dermatologic Diseases: Severe erythema multiforme, Stevens-Johnson syndrome 4. Edematous State: To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus 5. Ophthalmic Diseases: Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation 6. Respiratory Diseases: Symptomatic sarcoidosis 7. Rheumatic Disorders: psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis, ankylosing spondylitis 8. Any indication outside of the proven indications listed in the coverage criteria

3 . Revision History

Date	Notes
6/30/2022	Added a step through Cortrophin Gel for Acthar Gel under the OSM diagnosis.

Prior Authorization Guideline

GL-98979 Respiratory Agents - Cystic Fibrosis

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: Kalydeco, Orkambi, Symdeko, Trikafta	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of cystic fibrosis	

AND

2 - Prescribed by, or in consultation with a pulmonologist or infectious disease specialist

AND

3 - Patient meets the FDA-approved age minimum for the requested medication

AND

4 - Submission of chart documentation confirming the genetic mutation(s) that the FDA approved the requested medication to treat

Product Name: Bronchitol	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis

AND

2 - Prescribed by, or in consultation with a pulmonologist or infectious disease specialist

AND

3 - Patient meets the FDA-approved age minimum for the requested medication

AND

4 - Bronchitol will be used as an add-on maintenance therapy

AND

5 - Patients has passed the Bronchitol Tolerance Test

AND

6 - The patient cannot be changed to a preferred* medication due to ONE of the following acceptable reasons

6.1 Allergy to all preferred* medications

OR

6.2 Contraindication to or drug-to-drug interaction with preferred* medications

OR

6.3 History of unacceptable/toxic side effects to preferred* medications

Notes	*PDL: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Kalydeco, Orkambi, Symdeko, Trikafta, Bronchitol	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient continues to meet all initial authorization criteria

AND

2 - Patient's adherence to medication is confirmed by claim history

AND

3 - Submission of medical records (e.g., chart notes, laboratory tests/values, assessments) indicating stabilization OR improvement of forced expiratory volume (FEV1)

AND

4 - One or more of the following confirmed with submission of medical records (e.g., chart notes, laboratory tests/values, assessments)

- Stabilization or improvement of weight gain
- Stabilization or improvement in sweat chloride
- Decrease in the number of pulmonary exacerbations or their severity
- Decrease in the number or severity of pulmonary infections
- Decrease in the number of hospitalizations
- Increased Cystic Fibrosis Questionnaire-Revised (CFQ-R) respiratory domain score
- Other documentation by the physician clearly explaining the ongoing benefit of continuing the drug based on stated and documented objective evidence of improvement or a clear stabilization in a previous decline in one of the above parameters

2 . Revision History

Date	Notes
11/30/2021	Updated initial and re-auth criteria; Added criteria for Bronchitol

Prior Authorization Guideline

GL-107429 Respiratory Agents - Monoclonal Antibodies - Anti-IL, Anti-IgE

Formulary

Formulary Note

Guideline Note:

Effective Date:	7/1/2022

1 . Criteria

Product Name: Dupixent	
Diagnosis	Atopic dermatitis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe atopic dermatitis

AND

2 - Patient has a minimum body surface area (BSA) involvement of at least 10%

AND

3 - Prescribed by or in consultation with a dermatologist or allergist/immunologist

AND

4 - Prescribed in accordance with its FDA approved labeling

AND

5 - ONE of the following:

5.1 Patient has had inadequate response or contraindication to TWO of the following:

- Topical corticosteroids
- Topical calcineurin inhibitors (e.g., Elidel)
- Topical phosphodiesterase-4 (PDE-4) inhibitors (e.g., Eucrisa)

OR

5.2 Atopic dermatitis is severe and involves greater than 25% of BSA

Product Name: Dupixent	
Diagnosis	Atopic dermatitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Demonstration of improvement in patient's condition with Dupixent therapy [e.g., reduced body surface area (BSA) affected]

Product Name: Dupixent, Fasenra, Nucala, Xolair	
Diagnosis	Asthma
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe asthma

AND

2 - Prescribed by or in consultation with an allergist/immunologist or pulmonologist

AND

3 - Prescribed in accordance with its FDA approved labeling

AND

4 - Patient has uncontrolled asthma symptoms and/or exacerbations despite at least 30 days adherence to therapy with ONE of the following:

4.1 If patient is 6-11 years old: Medium dose preferred inhaled corticosteroids (ICS)/long-acting beta agonist (LABA) inhaler

OR

4.2 If patient is 12 years or older: Medium dose preferred inhaled corticosteroids (ICS)/long-acting beta agonist (LABA) inhaler with tiotropium or high dose preferred ICS/LABA inhaler

AND

5 - If the request is for a non-preferred* product, one of the following

5.1 Patient has uncontrolled asthma symptoms and/or exacerbations despite at least 90 days adherence to therapy with a preferred* medication

OR

5.2 ONE of the following:

- Allergy to all preferred medications
- Contraindication to or drug interaction to preferred medications
- History of unacceptable/toxic side effects to preferred medications

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Dupixent, Fasenra, Nucala, Xolair	
Diagnosis	Asthma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has demonstrated improvement with therapy (e.g. improvement in pulmonary function tests)

Product Name: Xolair	
Diagnosis	Chronic urticaria
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic urticaria

AND

2 - Prescribed by or in consultation with a dermatologist or allergist/immunologist

AND

3 - Prescribed in accordance with its FDA approved labeling

AND

4 - Patient has tried and failed TWO 14-day trials with two different antihistamines

Product Name: Dupixent, Nucala, Xolair	
Diagnosis	Nasal Polyps
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic rhinosinusitis with nasal polyposis

AND

2 - Prescribed by or in consultation with an allergist/immunologist, pulmonologist, or otolaryngologist

AND

3 - Prescribed in accordance with its FDA approved labeling

AND

4 - Patient had an inadequate response, intolerance or contraindication to a 30-day trial of BOTH of the following:

- One oral corticosteroid
- One nasal corticosteroid spray

2 . Revision History

Date	Notes
5/24/2022	Revised format of Guideline, separation based on Dx. Updated criteri a.

Prior Authorization Guideline

GL-99952 Respiratory Agents - Other Agents

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: Daliresp	
Approval Length	30 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Daliresp must be used with a long-acting beta agonist or long-acting muscarinic antagonists

2 . Revision History

Date	Notes
12/10/2021	Updated guideline name, criteria, approval duration, and note

Prior Authorization Guideline

GL-99104 Respiratory Agents-Inhaled Agents

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: Brand Xopenex and Xopenex concentrate, generic levalbuterol nebulizer solution, Brand Xopenex HFA, generic levalbuterol HFA, Proair Digihaler, Proair Respiclick, generic arformoterol, Brand Brovana, Brand Perforomist, generic formoterol, generic Ariduo Respiclick, generic fluticasone/salmeterol, Breo Ellipta, generic Wixela Inhub, Duaklir Pressair, Airduo Digihaler, Breztri, albuterol HFA, Proventil HFA, Lonhala Magnair, Tudorza, Yupelri, Bevespi, budesonide-formoterol (generic Symbicort)	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - The patient has a history of therapeutic failure to a 14-day trial of ONE preferred medication within the same drug class and formulation*

OR

2 - ONE of the following*:

- Allergy to preferred medications
- Contraindication to or drug interaction with preferred medications
- History of unacceptable or toxic side effects to preferred medications

Notes	*PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: Alvesco, Arnuity Ellipta, Asmanex HFA, QVAR Redihaler, Trelegy Ellipta, Armonair Digihaler	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a history of therapeutic failure to a 30-day trial of TWO preferred medications*

OR

2 - ONE of the following*:

- Allergy to preferred medications
- Contraindication to or drug interaction with preferred medications
- History of unacceptable or toxic side effects to preferred medications

OR

3 - BOTH of the following:

3.1 ONE of the following:

- Under the age of 13
- Disabled

AND

3.2 Unable to use a preferred inhaler

OR

4 - Non-compliant on a preferred inhaler due to taste, dry mouth, or infection

OR

5 - Clinically unstable, as defined in current guidelines in terms of oral steroid use or patient's current symptomatology

Notes	*PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: generic budesonide nebulizer suspension	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient is less than or equal to 6 years of age

OR

2 - The patient is over 6 years of age and ONE of the following:

2.1 BOTH of the following:

2.1.1 ONE of the following

- Under the age of 13
- Disabled

AND

2.1.2 Unable to use a preferred inhaler

OR

2.2 Non-compliant on a preferred inhaler due to taste, dry mouth, or infection

OR

2.3 Clinically unstable, as defined in current guidelines in terms of oral steroid use or patient's current symptomatology

Product Name: Brand Pulmicort nebulizer suspension	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient is less than or equal to 6 years of age

OR

2 - The patient is over 6 years of age and ONE of the following:

2.1 The patient has a history of therapeutic failure to a 30- day trial of TWO preferred medications*

OR

2.2 ONE of the following:*

- Allergy to preferred medications
- Contraindication to or drug interaction with preferred medications
- History of unacceptable or toxic side effects to preferred medications

OR

2.3 BOTH of the following:

2.3.1 ONE of the following

- Under the age of 13
- Disabled

AND

2.3.2 Unable to use a preferred inhaler

OR

2.4 Non-compliant on a preferred inhaler due to taste, dry mouth, or infection

OR

2.5 Clinically unstable, as defined in current guidelines in terms of oral steroid use or patient's current symptomatology

Notes	*PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

Product Name: albuterol soln nebu 0.63 mg/3mL & 1.25 mg/3mL	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria
1 - The patient is less than or equal to 12 years of age

2 . Revision History

Date	Notes
12/2/2021	Updated GPI table. Combined sections due to combined PDL sections. Added albuterol neb soln section for age review. Separated budesonide neb from Pulmicort neb to review for NP for Pulmicort.

Prior Authorization Guideline

GL-56808 Respiratory Agents: Leukotriene Receptor Modifiers and Inhibitors

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2020

1 . Criteria

Product Name: Zyflo, generic Zilueton ER	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has had a therapeutic failure to a 90 day trial of one preferred medication*

OR

2 - Patient has ONE of the following:

2.1 Patient has allergy to preferred medications

OR

2.2 Patient has a contraindication or drug-to-drug interaction with preferred medications

OR

2.3 Patient has a history of unacceptable/toxic side effects to preferred medications

Notes	*NOTE: PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html

Product Name: zafirlukast	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Patient has had a therapeutic failure of montelukast tablets, chewable tablets, or granules

2 . Revision History

Date	Notes
11/12/2019	C&S Implementation

Prior Authorization Guideline

GL-99089 Respiratory Agents: Antihistamines, Second Generation

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: Brand Zyrtec tab, cetirizine chewable tablets, Brand Zyrtec syrp (Zyrtec Children's Allergy), Brand Zyrtec-D, Brand Clarinex, generic desloratadine, Clarinex-D 12 hour, generic desloratadine ODT, Brand Allegra, generic fexofenadine tab, Brand Allegra susp, generic fexofenadine susp, Brand Xyzal tab and soln, generic levocetirizine tab and soln, Brand Claritin caps, generic loratadine caps, Brand Claritin tabs, Brand Claritin chewable tabs, generic loratadine chewable tabs, Brand Claritin syrup, Brand loratadine & pseudoephedrine ER 12 HR tab (Claritin-D 12 hour, Alavert, Wal-Itin D), Brand Claritin-D 24 hour, Brand loratadine rapidly disintegrating tabs (Claritin Reditabs, Alavert, Triaminic Allerchews)	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria **1** - The patient has had therapeutic failures after courses of treatment (e.g., 30 days for allergic rhinitis) with preferred medications* **OR** **2** - ONE of the following*: • Allergy to preferred medications • Contraindication to or drug interaction with preferred medications • History of unacceptable/toxic side effects to preferred medications	
Notes	*Note: PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
12/1/2021	Update

Prior Authorization Guideline

GL-56871 Respiratory Agents: Epinephrine Auto-Injectors

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2020

1 . Criteria

Product Name: Brand Epipen, generic epinephrine auto-injector (except Mylan), Brand Epipen JR, Auvi-Q	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following acceptable reasons the patient cannot be changed to a medication not requiring prior approval*:

- Intolerance to medication(s) not requiring prior approval
- Contraindication to or drug interaction with medication(s) not requiring prior approval

• History of unacceptable/toxic side effects to medications not requiring prior approval **OR** **2** - *The requested medication may be approved if there has been therapeutic failure using the product(s) not requiring prior approval	
Notes	*PDL Link: : https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
11/13/2019	New Program

Prior Authorization Guideline

GL-56931 Respiratory Agents: Nasal Preparations

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2020

1 . Criteria

Product Name: Beconase AQ, Rhinocort Allergy/Budesonide Nasal, Dymista, Brand Nasonex, generic mometasone, Omnaris, Qnasl, Xhance, Zetonna	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has had inadequate clinical response to two preferred or step therapy medications* (must be a 30 day trial of each medication)	

OR **2** - Patient has ONE of the following: **2.1** Allergy to preferred medications **OR** **2.2** Contraindication or drug interaction with preferred medications **OR** **2.3** History of unacceptable/toxic side effects to preferred medications	
Notes	*PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
11/14/2019	C&S Implementation

Prior Authorization Guideline

GL-56872 Respiratory Agents: Hereditary Angioedema

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2020

1 . Criteria

Product Name: Berinert, Cinryze, Brand Firazyr, generic Icatibant, Haegarda, Kalbitor, Ruconest, Takhzyro	
Diagnosis	Hereditary Angioedema
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of hereditary angioedema	

AND

2 - History of recurrent angioedema (without urticaria) within the past 6 months

AND

3 - History of recurrent episodes of abdominal pain and vomiting within the past 6 months

AND

4 - History of laryngeal edema within the past 180 days

AND

5 - Positive family history of angioedema

AND

6 - If the request is for a non-preferred medication, ONE of the following:

- One episode of angioedema during use of a preferred medication
- Allergy to preferred medications
- Contraindication or drug interaction with preferred medications
- History of unacceptable/toxic side effects to preferred medications

Notes	*PDL Link: : https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
11/13/2019	New Program

Prior Authorization Guideline

GL-90195 Retevmo

Formulary

Formulary Note

Guideline Note:

Effective Date:	10/1/2021

1 . Criteria

Product Name: Retevmo	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of non-small cell lung cancer (NSCLC)	

AND

2 - Disease is ONE of the following:

- Recurrent
- Advanced
- Metastatic

AND

3 - Presence of RET gene fusion-positive or RET rearrangement positive tumors

Product Name: Retevmo	
Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ALL of the following:

1.1.1 Diagnosis of medullary thyroid cancer (MTC)

AND

1.1.2 Disease is ONE of the following:

- Advanced
- Metastatic

AND

1.1.3 Disease has presence of RET gene mutation

AND

1.1.4 Disease requires treatment with systemic therapy

OR

1.2 ALL of the following:

1.2.1 Diagnosis of thyroid cancer

AND

1.2.2 Disease is ONE of the following:

- Advanced
- Metastatic

AND

1.2.3 Disease is RET gene fusion-positive

AND

1.2.4 Disease requires treatment with systemic therapy

AND

1.2.5 One of the following:

- Patient is radioactive iodine-refractory
- Treatment with radioactive iodine is not appropriate

Product Name: Retevmo	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following histiocytic neoplasms:

- Langerhans Cell Histiocytosis
- Erdheim-Chester disease
- Rosai-Dorfman disease

AND

2 - Used for RET fusion target as a single agent

Product Name: Retevmo	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC), Thyroid Cancer, Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Retevmo therapy

Product Name: Retevmo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Retevmo will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Retevmo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Retevmo therapy

2 . Revision History

Date	Notes
7/21/2021	Copy of NY GL-90180

Prior Authorization Guideline

GL-108429 Revlimid

Formulary

Formulary Note

Guideline Note:

Effective Date:	8/1/2022

1 . Criteria

Product Name: Brand Revlimid, generic lenalidomide	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has a diagnosis of multiple myeloma	

Product Name: Brand Revlimid, generic lenalidomide	
Diagnosis	Myelodysplastic Syndromes (MDS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of symptomatic anemia due to myelodysplastic syndrome (MDS) associated with a deletion 5q

OR

2 - BOTH of the following:

2.1 Patient has a diagnosis of anemia due to myelodysplastic syndrome WITHOUT deletion 5q

AND

2.2 ONE of the following:

2.2.1 Serum erythropoetin levels greater than 500 mU (milliunits)/mL (milliliter)

OR

2.2.2 ALL of the following:

2.2.2.1 Serum erythropoetin levels less than or equal to 500 mU/mL

AND

2.2.2.2 Ring sideroblasts less than 15%

AND

2.2.2.3 ONE of the following:

- Revlimid therapy is in combination with an erythropoietin [e.g., Epogen, Procrit, Retacrit (epoetin alfa)]
- Failure to erythropoietins [e.g., Epogen, Procrit, Retacrit (epoetin alfa)] as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to erythropoietins [e.g., Epogen, Procrit, Retacrit (epoetin alfa)] (please specify contraindication or intolerance)

OR

2.2.3 ALL of the following:

2.2.3.1 Serum erythropoetin levels less than or equal to 500 mU/mL

AND

2.2.3.2 Ring sideroblasts greater than or equal to 15%

AND

2.2.3.3 No response to an erythropoietin in combination with a granulocyte-colony stimulating factor (G-CSF)

OR

3 - BOTH of the following:

3.1 Diagnosis of myelodysplastic/myeloproliferative neoplasms (MDS/MPN) overlap neoplasm

AND

3.2 Patient has ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)

Product Name: Brand Revlimid, generic lenalidomide

Diagnosis	B-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Mantle cell lymphoma (MCL)
- Diffuse large B-cell lymphoma (patients 60 to 80 years old)
- Follicular lymphoma
- Gastric mucosa-associated lymphoid tissue (MALT) lymphoma
- Nodal marginal zone lymphoma
- Non-gastric MALT lymphoma
- Splenic marginal zone lymphoma

OR

2 - BOTH of the following:

2.1 ONE of the following diagnoses:

- Acquired immunodeficiency syndrome (AIDS)-related B-cell lymphoma
- Castleman's Disease (CD)
- Diffuse large B-cell lymphoma (patients who are less than 60 years old)
- High-grade B-cell lymphoma
- Histologic transformation of marginal zone lymphoma to diffuse large B-cell lymphoma
- Post-transplant lymphoproliferative disorders

AND

2.2 NOT used as first line therapy

Product Name: Brand Revlimid, generic lenalidomide	
Diagnosis	Hodgkin Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of Hodgkin lymphoma

AND

2 - Disease is ONE of the following:

- Relapsed
- Refractory

AND

3 - Used as third-line or subsequent therapy

Product Name: Brand Revlimid, generic lenalidomide	
Diagnosis	Systemic Light Chain Amyloidosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of systemic light chain amyloidosis

AND

2 - ONE of the following:

2.1 Used in combination with dexamethasone

OR

2.2 Used in combination with dexamethasone and cyclophosphamide

OR

2.3 Used in combination with dexamethasone and Ninlaro (ixazomib)

Product Name: Brand Revlimid, generic lenalidomide	
Diagnosis	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)

AND

2 - ONE of the following:

- Used post first-line chemoimmunotherapy maintenance therapy
- Used post second-line maintenance therapy
- Used for relapsed or refractory disease

Product Name: Brand Revlimid, generic lenalidomide	
Diagnosis	T-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

- Peripheral T-cell lymphoma
- T-cell leukemia/lymphoma
- Hepatosplenic gamma-delta T-cell lymphoma

AND

2 - NOT used as first line therapy

Product Name: Brand Revlimid, generic lenalidomide	
Diagnosis	Primary CNS Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of primary central nervous system lymphoma

Product Name: Brand Revlimid, generic lenalidomide	
Diagnosis	Kaposi Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 ONE of the following:

1.1.1 Patient has a diagnosis of human immunodeficiency virus (HIV)-negative Kaposi Sarcoma

OR

1.1.2 BOTH of the following:

1.1.2.1 Diagnosis of AIDS-related Kaposi Sarcoma

AND

1.1.2.2 Patient is currently being treated with antiretroviral therapy (ART) confirmed by claims history or submission of medical records

AND

1.2 NOT used as first line therapy

Product Name: Brand Revlimid, generic lenalidomide	
Diagnosis	Langerhans Cell Histiocytosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Langerhans cell histiocytosis

Product Name: Brand Revlimid, generic lenalidomide	
Diagnosis	*
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Revlimid therapy

Notes	*Multiple Myeloma, Myelodysplastic Syndromes (MDS), B-Cell Lymphomas, Hodgkin Lymphoma, Systemic Light Chain Amyloidosis, Chroni

	c Lymphocytic Leukemia/Small Lymphocytic Lymphoma, T-Cell Lymphomas, Primary CNS Lymphomas, Kaposi Sarcoma, Langerhans Cell Histiocytosis

Product Name: Brand Revlimid, generic lenalidomide	
Diagnosis	Myelofibrosis-Associated Anemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of myelofibrosis

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 Serum erythropoietin levels less than 500 mU (milliunits)/mL (milliliter)

AND

2.1.2 ONE of the following:

2.1.2.1 Failure to erythropoietins [e.g., Procrit (epoetin alfa)] as confirmed by claims history or submission of medical records

OR

2.1.2.2 History of contraindication or intolerance to erythropoietins [e.g., Procrit (epoetin alfa)] (please specify contraindication or intolerance)

OR

2.2 Serum erythropoietin levels greater than or equal to 500 mU/mL

Product Name: Brand Revlimid, generic lenalidomide	
Diagnosis	Myelofibrosis-Associated Anemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation that the patient has evidence of symptom improvement or reduction in spleen/liver volume while on Revlimid

Product Name: Brand Revlimid, generic lenalidomide	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Revlimid will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Brand Revlimid, generic lenalidomide	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Revlimid therapy

2 . Revision History

Date	Notes
6/20/2022	Added generic lenalidomide. Updated criteria to remove primary cutaneous lymphoma according to NCCN guidelines. Added criteria to be used in combination with dexamethasone and Ninlaro for systemic light chain amyloidosis. Updated Kaposi Sarcoma according to NCCN guidelines. Updated trial, failure, contraindication language throughout.

Prior Authorization Guideline

GL-108546 Rezurock

Formulary

Formulary Note

Guideline Note:

Effective Date:	7/1/2022

1 . Criteria

Product Name: Rezurock	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chronic graft-versus-host disease (chronic GVHD)	

AND

2 - History of failure of at least TWO prior lines of systemic therapy (e.g., corticosteroids, mycophenolate, tacrolimus, etc.)

AND

3 - The patient is at least 12 years of age

Product Name: Rezurock	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Rezurock therapy

Prior Authorization Guideline

GL-57022 Rozlytrek

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2020

1 . Criteria

Product Name: Rozlytrek	
Diagnosis	Non-small cell lung cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has diagnosis of metastatic non-small cell lung cancer (NSCLC)

AND

2 - Disease is ROS1-positive

Product Name: Rozlytrek	
Diagnosis	NTRK gene fusion-positive solid tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Presence of solid tumors (e.g., sarcoma, non-small cell lung cancer [NSCLC], salivary, breast, thyroid, colorectal, neuroendocrine, pancreatic, gynecological, cholangiocarcinoma, etc.)

AND

2 - Disease is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion (e.g. ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

3 - Disease is without a known acquired resistance mutation [e.g., TRKA G595R substitution, TRKA G667C substitution, or other recurrent kinase domain (solvent front and xDFG) mutations]

AND

4 - Disease is ONE of the following:

- Metastatic
- Unresectable

AND

5 - ONE of the following:

5.1 Disease has progressed on previous treatment (e.g.surgery, radiotherapy, or systemic therapy)

OR

5.2 Disease has no satisfactory alternative treatments

Product Name: Rozlytrek	
Diagnosis	Non-small cell lung cancer (NSCLC), NTRK gene fusion-positive solid tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Rozlytrek therapy

Product Name: Rozlytrek	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Rozlytrek will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Rozlytrek

Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Rozlytrek therapy

2 . Revision History

Date	Notes
11/15/2019	C&S Implementation

Prior Authorization Guideline

GL-109374 Rubraca

Formulary

Formulary Note

Guideline Note:

Effective Date:	9/1/2022

1 . Criteria

Product Name: Rubraca	
Diagnosis	Epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of ONE of the following:	

- Epithelial ovarian cancer
- Fallopian tube cancer
- Primary peritoneal cancer

AND

2 - ONE of the following:

2.1 BOTH of the following

2.1.1 Cancer has a deleterious BRCA mutation

AND

2.1.2 History of failure, contraindication, or intolerance to TWO or more chemotherapies (e.g., carboplatin or cisplatin)

OR

2.2 To be used as maintenance therapy in individuals who are in complete or partial response to platinum-based chemotherapy

Product Name: Rubraca	
Diagnosis	Prostate cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic, castration-resistant prostate cancer

AND

2 - Cancer has a deleterious BRCA mutation

AND

3 - ONE of the following:

3.1 Failure to androgen receptor-directed therapy [e.g., Zytiga (abiraterone), Xtandi (enzalutamide), Erleada (apalutamide)] as confirmed by claims history or submission of medical records

OR

3.2 Contraindication or intolerance to androgen receptor-directed therapy [e.g., Zytiga (abiraterone), Xtandi (enzalutamide), Erleada (apalutamide)] (please specify intolerance or contraindication

AND

4 - History of failure, contraindication, or intolerance to taxane-based chemotherapy (e.g., docetaxel, Jevtana (cabazitaxel))

AND

5 - ONE of the following:

5.1 Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

OR

5.2 Patient has had bilateral orchiectomy

Product Name: Rubraca	
Diagnosis	Uterine cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of BRCA altered uterine leiomyosarcoma (uLMS)

AND

2 - Disease has progressed following prior treatment with ONE of the following:

- Gemcitabine plus docetaxel
- Doxorubicin

Product Name: Rubraca	
Diagnosis	Pancreatic cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pancreatic adenocarcinoma

AND

2 - Disease is metastatic

AND

3 - Presence of ONE of the following:

3.1 Deleterious or suspected deleterious germline or somatic BRCA1/2 mutation

OR

3.2 Deleterious or suspected deleterious germline or somatic PALB2 mutation

AND

4 - Disease has NOT progressed while receiving at least 16 weeks of a first-line platinum-based chemotherapy regimen

Product Name: Rubraca	
Diagnosis	Epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, Prostate cancer, Uterine cancer, Pancreatic cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does NOT show evidence of progressive disease while on Rubraca therapy

Product Name: Rubraca	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Rubraca

Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Rubraca therapy

2 . Revision History

Date	Notes
7/14/2022	Updated criteria to include indications for uterine cancer and pancrea tic cancer per NCCN guidelines. Updated step therapy language. Up dated capitalization throughout guideline.

Prior Authorization Guideline

GL-89855 Rydapt

Formulary

Formulary Note

Guideline Note:

Effective Date:	9/1/2021

1 . Criteria

Product Name: Rydapt	
Diagnosis	Acute Myeloid Leukemia (AML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - AML is FLT3 mutation-positive

AND

3 - Rydapt will be used in combination with standard induction and consolidation therapy

Product Name: Rydapt	
Diagnosis	Systemic Mastocytosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Aggressive systemic mastocytosis (ASM)
- Systemic mastocytosis with associated hematologic neoplasm (SM-AHN)
- Mast cell leukemia (MCL)

Product Name: Rydapt	
Diagnosis	Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia

AND

2 - ONE of the following:

- Patient has a FGFR1 rearrangement
- Patient has a FLT3 rearrangement

Product Name: Rydapt	
Diagnosis	Acute Myeloid Leukemia (AML), Systemic Mastocytosis, Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Rydapt therapy

Product Name: Rydapt	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Rydapt	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Rydapt therapy	

2 . Revision History

Date	Notes
7/13/2021	Copied from NY. Added myeloid/lymphoid neoplasms criteria per NCCN guideline update.

Prior Authorization Guideline

GL-89166 Samsca

Formulary

Formulary Note

Guideline Note:

Effective Date:	9/1/2021

1 . Criteria

Product Name: Brand Samsca, generic tolvaptan	
Approval Length	30 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

- Diagnosis of clinically significant euvolemic hyponatremia
- Diagnosis of clinically significant hypervolemic hyponatremia

AND

2 - Patient has not responded to fluid restriction

AND

3 - Treatment has been initiated or re-initiated in a hospital setting prior to discharge

Prior Authorization Guideline

GL-102869 Sandostatin

Formulary

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Brand Sandostatin, generic octreotide	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of acromegaly	

AND

2 - One of the following:

2.1 Inadequate response to one of the following:

- Surgery
- Radiotherapy
- Dopamine agonist (e.g., bromocriptine, cabergoline) therapy

OR

2.2 Not a candidate for all of the following:

- Surgery
- Radiotherapy
- Dopamine agonist (e.g., bromocriptine, cabergoline) therapy

Product Name: Brand Sandostatin, generic octreotide	
Diagnosis	Meningioma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of meningioma

AND

2 - Disease is surgically inaccessible

AND

3 - One of the following:

- Disease is recurrent
- Disease is progressive

AND

4 - Additional radiation is not possible

Product Name: Brand Sandostatin, generic octreotide	
Diagnosis	Neuroendocrine and Adrenal Tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has neuroendocrine tumors [e.g., carcinoid tumors, Islet cell tumors, gastrinomas, glucagonomas, insulinomas, lung tumors, somatostatinomas, tumors of the pancreas, GI (gastrointestinal) tract, lung and thymus, adrenal glands, and vasoactive intestinal polypeptidomas (VIPomas)]

OR

2 - All of the following:

- Diagnosis of Pheochromocytoma or Paraganglioma
- Disease is locally unresectable or distant metastases
- Disease is somatostatin receptor positive
- Presence of symptomatic disease

Product Name: Brand Sandostatin, generic octreotide	
Diagnosis	Neuroendocrine and Adrenal Tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on the requested therapy

OR

2 - Documentation of positive clinical response (e.g. suppression of severe diarrhea, flushing, etc.) to the requested therapy

Product Name: Brand Sandostatin, generic octreotide	
Diagnosis	Thymoma or Thymic Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of thymoma or thymic carcinoma

AND

2 - ONE of the following:

2.1 Used as a second-line therapy for one of the following:

2.1.1 Unresectable disease following first-line chemotherapy for potentially resectable locally advanced disease, solitary metastasis, or ipsilateral pleural metastasis

OR

2.1.2 Extrathoracic metastatic disease

OR

2.2 BOTH of the following:

2.2.1 Used as first line therapy for one of the following:

- Unresectable locally advanced disease in combination with radiation therapy
- Potentially resectable locally advanced disease
- Potentially resectable solitary metastasis or ipsilateral pleural metastasis
- Consideration following surgery for solitary metastasis or ipsilateral pleural metastasis
- Extrathoracic metastatic disease
- Postoperative treatment for thymic carcinoma after R1/R2 resection or thymoma after R2 resection

AND

2.2.2 Patient is unable to tolerate first-line combination regimens

Product Name: Brand Sandostatin, generic octreotide	
Diagnosis	Meningioma, Thymoma or Thymic Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on the requested therapy

Product Name: Brand Sandostatin, generic octreotide	
Diagnosis	Malignant Bowel Obstruction
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of malignant bowel obstruction

AND

2 - Gut function cannot be maintained

Product Name: Brand Sandostatin, generic octreotide	
Diagnosis	Chemotherapy- and/or Radiation-Induced Diarrhea
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of diarrhea due to concurrent cancer chemotherapy and/or radiation

AND

2 - One of the following:

2.1 Presence of Grade 3 or 4 severe diarrhea

OR

2.2 Patient is in palliative or end of life care

Product Name: Brand Sandostatin, generic octreotide	
Diagnosis	HIV/AIDS-Related Diarrhea
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HIV (human immunodeficiency virus)/AIDS (acquired immunodeficiency syndrome)-related diarrhea

Product Name: Brand Sandostatin, generic octreotide	
Diagnosis	Bleeding Gastroesophageal Varices
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of bleeding gastroesophageal varices associated with liver disease

Product Name: Brand Sandostatin, generic octreotide	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Brand Sandostatin, generic octreotide	
Diagnosis	Acromegaly, Malignant Bowel Obstruction, Chemotherapy- and/or Radiation-Induced Diarrhea, HIV/AIDS-Related Diarrhea, Bleeding Gastroesophageal Varices, NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to the requested therapy

2 . Revision History

Date	Notes
1/24/2022	Revised coverage criteria for thymoma to include postoperative treat ment for thymic carcinoma in accordance with NCCN guidelines.

Prior Authorization Guideline

GL-101081 Scemblix

Formulary

Formulary Note

Guideline Note:

Effective Date:	3/1/2022

1 . Criteria

Product Name: Scemblix	
Diagnosis	Philadelphia Chromosome-Positive Chronic Myeloid Leukemia (Ph+CML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chronic myeloid leukemia (CML)	

AND

2 - Disease is Philadelphia chromosome-positive (Ph+)

AND

3 - Disease is in chronic phase

AND

4 - ONE of the following:

- Patient has been previously treated with two or more tyrosine kinase inhibitors [e.g., Bosulif (bosutinib), imatinib (Gleevec) Sprycel [dasatinib], Tasigna (nilotinib)]
- Disease is T315I mutation positive

Product Name: Scemblix	
Diagnosis	Philadelphia Chromosome-Positive Chronic Myeloid Leukemia (Ph+CML)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Scemblix therapy

Product Name: Scemblix	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Scemblix	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Scemblix therapy

2 . Revision History

Date	Notes
12/28/2021	Copy NY

Prior Authorization Guideline

GL-62948 Sensipar

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Brand Sensipar, generic cinacalcet	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescribed by or in consultation with an oncologist, endocrinologist, or nephrologist

AND

2 - One of the following:

2.1 All of the following:

2.1.1 Diagnosis of secondary hyperparathyroidism with chronic kidney disease

AND

2.1.2 Patient is on dialysis

AND

2.1.3 Both of the following:

- Patient has therapeutic failure, contraindication, or intolerance to one phosphate binder (e.g., PhosLo, Fosrenol, Renvela, Renagel, etc.)
- Patient has therapeutic failure, contraindication, or intolerance to one vitamin D analog (e.g., calcitriol, Hectorol, Zemplar, etc.)

OR

2.2 Diagnosis of hypercalcemia with parathyroid carcinoma

OR

2.3 Both of the following:

- Diagnosis of severe hypercalcemia (level greater than 12.5 milligrams per deciliter) with primary hyperparathyroidism
- Patient is unable to undergo parathyroidectomy

Product Name: Brand Sensipar, generic cinacalcet	
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has experienced a reduction in serum calcium from baseline	

2 . Revision History

Date	Notes
3/9/2020	2020 Implementation

Prior Authorization Guideline

GL-56592 Signifor

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2020
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Signifor	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Both of the following:	

1.1 Diagnosis of endogenous Cushing's disease (i.e., hypercortisolism is not a result of chronic administration of high dose glucocorticoids)

AND

1.2 One of the following:

- Pituitary surgery has not been curative for the patient
- Patient is not a candidate for pituitary surgery

Product Name: Signifor	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Signifor therapy

2 . Revision History

Date	Notes
11/6/2019	New Guideline.

Prior Authorization Guideline

GL-96345 Sivextro

Formulary

Formulary Note

Guideline Note:

Effective Date:	12/1/2021

1 . Criteria

Product Name: Sivextro	
Diagnosis	Skin and Skin Structure Infections
Approval Length	6 Day(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - For continuation of therapy upon hospital discharge	

OR

2 - As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR

3 - ALL of the following:

3.1 Diagnosis of acute bacterial skin and skin structure infection (including diabetic foot infections)

AND

3.2 ONE of the following:

3.2.1 BOTH of the following:

3.2.1.1 Acute bacterial skin and skin structure infections

AND

3.2.1.2 Infection caused by methicillin-resistant Staphylococcus aureus (MRSA) documented by culture and sensitivity report

OR

3.2.2 BOTH of the following:

3.2.2.1 Empirical treatment of patients with acute bacterial skin and skin structure infections

AND

3.2.2.2 Presence of MRSA infection is likely

AND

3.3 History of failure, contraindication, or intolerance to linezolid (generic Zyvox)

AND

3.4 History of failure, contraindication, or intolerance to ONE of the following antibiotics:

- Sulfamethoxazole-trimethoprim (SMX-TMP)
- A tetracycline
- Clindamycin

OR

4 - ALL of the following:

4.1 Diagnosis of acute bacterial skin and skin structure infection (including diabetic foot infections)

AND

4.2 Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Sivextro

AND

4.3 History of failure, contraindication, or intolerance to linezolid (generic Zyvox)

AND

4.4 History of failure, contraindication, or intolerance to TWO of the following antibiotics:

- Dicloxacillin
- A cephalosporin
- A tetracycline
- Amoxicillin/clavulanate

- Clindamycin
- Sulfamethoxazole-trimethoprim (SMX-TMP)
- A fluoroquinolone

Product Name: Sivextro	
Diagnosis	Off-Label Uses
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of therapy upon hospital discharge

OR

2 - As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR

3 - BOTH of the following:

3.1 The drug has been recognized for treatment of the indication by the Infectious Diseases Society of America (IDSA)

AND

3.2 History of failure, contraindication, or intolerance to linezolid (generic Zyvox), when susceptibility is confirmed by culture

Notes	Approval Duration is based on provider and IDSA recommended treat ment durations, up to 6 months.

Prior Authorization Guideline

GL-56591 Somavert

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2020
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Somavert	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - All of the following:

1.1 Diagnosis of acromegaly by ONE of the following:

- Serum GH (growth hormone) level greater than 1 ng/mL (nanograms per milliliter) after a 2 hour oral glucose tolerance test (OGTT) at time of diagnosis
- Elevated serum IGF-1 (Insulin-like growth factor-1) levels (above the age and gender adjusted normal range as provided by the physician's lab) at time of diagnosis

AND

1.2 One of the following:

1.2.1 Inadequate response to one of the following:

- Surgery
- Radiation therapy
- Dopamine agonist (e.g., bromocriptine, cabergoline) therapy

OR

1.2.2 Not a candidate for all of the following:

- Surgery
- Radiation therapy
- Dopamine agonist (e.g., bromocriptine, cabergoline) therapy

AND

1.3 Inadequate response, intolerance, or contraindication to one of the following somatostatin analogs:

- Sandostatin (octreotide) or Sandostatin LAR
- Somatuline Depot (lanreotide)

OR

2 - Patient is currently on Somavert therapy for acromegaly

Product Name: Somavert	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Somavert therapy

2 . Revision History

Date	Notes
11/6/2019	New Guideline.

Prior Authorization Guideline

GL-103980 Soriatane (acitretin)

Formulary

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Generic Acitretin	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of severe psoriasis	

AND

2 - Prescribed by, or in consultation with, a dermatologist

AND

3 - History of failure to a 3 month trial of methotrexate at the maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)

AND

4 - One of the following:

- Greater than or equal to 10% body surface area involvement
- Palmoplantar, facial, or genital involvement
- Severe scalp psoriasis

Product Name: Generic acitretin	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Soriatane therapy

AND

2 - Prescribed by, or in consultation with, a dermatologist

2 . Revision History

Date	Notes
2/22/2022	Copy NY; removal of brand- no longer available. Updated Guideline name to include generic.

Prior Authorization Guideline

GL-109875 Spravato

Formulary

Formulary Note

Guideline Note:

Effective Date:	9/1/2022

1 . Criteria

Product Name: Spravato	
Diagnosis	Major Depressive Disorder (Treatment-Resistant)
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of major depressive disorder (treatment-resistant), according to the current Diagnostic and Statistical Manual of Mental Disorders (DSM) (i.e., DSM-5) criteria, by a mental health professional

AND

2 - Prescribed by or in consultation with a psychiatrist

AND

3 - Submission of medical records (e.g., chart notes, laboratory values) documenting baseline scoring (prior to starting Spravato) on at least ONE of the following clinical assessments has been completed:

- Baseline score on the 17-item Hamilton Rating Scale for Depression (HAMD17)
- Baseline score on the 16-item Quick Inventory of Depressive Symptomatology (QIDS-C16)
- Baseline score on the 10-item Montgomery-Asberg Depression Rating Scale (MADRS)

AND

4 - ONE of the following:

4.1 Failure of THREE different antidepressant medications or treatment regimens at the maximally tolerated dose(s) for at least 8 weeks in the current depressive episode, confirmed by claims history or submitted medical records. An antidepressant or treatment regimen would include any of the following classes or combinations:

- Selective serotonin reuptake inhibitors (e.g., citalopram, fluoxetine, paroxetine, sertraline)
- Serotonin norepinephrine reuptake inhibitors (e.g., duloxetine, venlafaxine, etc.)
- Bupropion
- Tricyclic antidepressants (e.g., amitriptyline, clomipramine, nortriptyline, etc.)
- Mirtazapine
- Monoamine oxidase inhibitors (e.g., selegiline, tranylcypromine, etc.)
- Serotonin modulators (e.g., nefazodone, trazodone, etc.)
- Augmentation with lithium, Cytomel (liothyronine), antipsychotics, or anticonvulsants

OR

4.2 History of intolerance or contraindication to THREE of the following antidepressant medications or treatment regimens (please specify intolerance or contraindication). An

antidepressant or treatment regimen would include any of the following classes or combinations:

- Selective serotonin reuptake inhibitors (e.g., citalopram, fluoxetine, paroxetine, sertraline)
- Serotonin norepinephrine reuptake inhibitors (e.g., duloxetine, venlafaxine, etc.)
- Bupropion
- Tricyclic antidepressants (e.g., amitriptyline, clomipramine, nortriptyline, etc.)
- Mirtazapine
- Monoamine oxidase inhibitors (e.g., selegiline, tranylcypromine, etc.)
- Serotonin modulators (e.g., nefazodone, trazodone, etc.)
- Augmentation with lithium, Cytomel (liothyronine), antipsychotics, or anticonvulsants

AND

5 - Spravato will be initiated at the same time the patient starts a new daily oral antidepressant (one that has not previously been tried)

AND

6 - Provider and/or the provider's healthcare setting is certified in the Spravato REMS (Risk Evaluation and Mitigation Strategy) program

Product Name: Spravato	
Diagnosis	Major Depressive Disorder (Treatment-Resistant)
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of remission or a positive clinical response to Spravato therapy

AND

2 - Spravato will be used in combination with an oral antidepressant (confirmed by claims history or submitted medical records)

AND

3 - Submission of medical records (e.g., chart notes, laboratory values) documenting baseline and recent (within the last month) scoring on at least ONE of the following assessments demonstrating remission or clinical response (e.g., score reduction from baseline) as defined by:

- Hamilton Rating Scale for Depression (HAMD17; remission defined as a score of less than or equal to 7)
- Quick Inventory of Depressive Symptomatology (QIDS-C16; remission defined as a score of less than or equal to 5)
- Montgomery-Asberg Depression Rating Scale (MADRS; remission defined as a score of less than or equal to 12)

AND

4 - Provider and/or the provider's healthcare setting is certified in the Spravato REMS (Risk Evaluation and Mitigation Strategy) program

AND

5 - Prescribed by or in consultation with a psychiatrist

Product Name: Spravato*	
Diagnosis	Depressive symptoms in an adult with major depressive disorder (MDD) with acute suicidal ideation or behavior
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of major depressive disorder according to the current Diagnostic and Statistical Manual of Mental Disorders (DSM) (i.e., DSM-5) criteria, by a mental health professional

AND

2 - Patient is experiencing an acute suicidal ideation or behavior **AND** **3** - Patient is receiving newly initiated or optimized oral antidepressant **AND** **4** - Provider and/or the provider’s healthcare setting is certified in the Spravato REMS (Risk Evaluation and Mitigation Strategy) program

Notes	*Spravato is hard-coded with a quantity of 0.29 per day for the 56mg s trength and 0.43 per day for the 84mg strength. If criteria are met, ent er one GPI-12 authorization with an MDD override of 0.86.

Product Name: Spravato*	
Diagnosis	Depressive symptoms in an adult with major depressive disorder (MDD) with acute suicidal ideation or behavior
Approval Length	1 month(s)
Guideline Type	Quantity Limit

Approval Criteria **1** - Spravato is prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in the compendia of current literature

Notes	*Spravato is hard-coded with a quantity of 0.29 per day for the 56mg s trength and 0.43 per day for the 84mg strength. If criteria are met, ent er one GPI-12 authorization with an MDD override of 0.86.

2 . Revision History

Date	Notes
7/27/2022	Updated diagnosis section of QL with "Depressive symptoms in an a dult with MDD with acute suicidal ideation or behavior"

Prior Authorization Guideline

GL-97056 Sprycel

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: Sprycel	
Diagnosis	Philadelphia chromosome-positive or BCR-ABL1-positive chronic myeloid leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Philadelphia chromosome-positive or BCR-ABL1-positive chronic myeloid leukemia

AND

2 - One of the following:

2.1 Patient is not a candidate for imatinib as attested by physician

OR

2.2 Patient is currently on Sprycel therapy

Product Name: Sprycel	
Diagnosis	Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL)

Product Name: Sprycel	
Diagnosis	Gastrointestinal stromal tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumor (GIST) with PDGFRA D842V mutation

Product Name: Sprycel

Diagnosis	Chondrosarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic chondrosarcoma

Product Name: Sprycel	
Diagnosis	Chordoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent chordoma

Product Name: Sprycel	
Diagnosis	Myeloid/Lymphoid neoplasms with eosinophilia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia

AND

2 - Patient has an ABL1 (gene) rearrangement

Product Name: Sprycel	
Diagnosis	Philadelphia chromosome-positive or BCR-ABL1-positive chronic myeloid leukemia, Ph+ALL, GIST, Chondrosarcoma, Chordoma, Myeloid/Lymphoid neoplasms with eosinophilia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Sprycel therapy

Product Name: Sprycel	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Sprycel	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Sprycel therapy

Prior Authorization Guideline

GL-109640 Stivarga

Formulary

Formulary Note

Guideline Note:

Effective Date:	9/1/2022

1 . Criteria

Product Name: Stivarga	
Diagnosis	Colorectal Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced or metastatic colorectal cancer

AND

2 - History of failure, contraindication, or intolerance to treatment with all of the following:

- Oxaliplatin-based chemotherapy
- Irinotecan-based chemotherapy
- Fluoropyrimidine-based chemotherapy
- Anti-VEGF therapy-based chemotherapy

AND

3 - ONE of the following:

3.1 Tumor is RAS mutant-type

OR

3.2 BOTH of the following:

3.2.1 Tumor is RAS wild-type

AND

3.2.2 History of failure, contraindication, or intolerance to anti-EGFR therapy

Product Name: Stivarga	
Diagnosis	Soft Tissue Sarcoma (STS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of soft tissue sarcoma (STS)

AND

1.2 ONE of the following:

1.2.1 Extremity/superficial trunk or nead/neck that is non-adipocytic with advanced/metastatic disease with disseminated metastases

OR

1.2.2 Retroperitoneal/intra-abdominal that is non-adipocytic with recurrent unresectable or stage IV disease

OR

1.2.3 Pleomorphic rhabdomyosarcoma

OR

1.2.4 Angiosarcoma

OR

2 - ALL of the following:

2.1 Diagnosis of gastrointestinal stromal tumor (GIST)

AND

2.2 Disease is one of the following:

- Progressive
- Locally advanced
- Unresectable

- Metastatic

AND

2.3 ONE of the following:

2.3.1 Failure of ONE of the following confirmed by claims history or submitted medical records:

- imatinib mesylate (generic Gleevec)
- sunitinib maleate (generic Sutent)

OR

2.3.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- imatinib mesylate (generic Gleevec)
- sunitinib maleate (generic Sutent)

Product Name: Stivarga	
Diagnosis	Hepatobiliary Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of one of the following:

- Gallbladder cancer
- Extrahepatic cholangiocarcinoma
- Intrahepatic cholangiocarcinoma

AND

1.2 Disease is unresectable or metastatic

OR

2 - ALL of the following:

2.1 Diagnosis of hepatocellular carcinoma

AND

2.2 ONE of the following:

2.2.1 Failure to Nexavar (sorafenib tosylate) confirmed by claims history or submitted medical records

OR

2.2.2 History of intolerance or contraindication to Nexavar (sorafenib tosylate) (please specify intolerance or contraindication)

Product Name: Stivarga	
Diagnosis	Osteosarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Osteosarcoma
- Dedifferentiated chondrosarcoma
- High grade undifferentiated pleomorphic sarcoma (UPS)

AND

2 - Disease is one of the following:

- Relapsed/refractory
- Metastatic

AND

3 - Used as second-line therapy

Product Name: Stivarga	
Diagnosis	Glioblastoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent glioblastoma

Product Name: Stivarga	
Diagnosis	Colorectal Cancer, Soft Tissue Sarcoma (STS), Hepatobiliary Cancers, Osteosarcoma, Glioblastoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Stivarga therapy

Product Name: Stivarga	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Stivarga	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Stivarga therapy

Prior Authorization Guideline

GL-109566 Strensiq

Formulary

Formulary Note

Guideline Note:

Effective Date:	9/1/2022

1 . Criteria

Product Name: Strensiq	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of perinatal/infantile or juvenile-onset hypophosphatasia based on ALL of the following:

1.1 ONE of the following:

1.1.1 Onset of clinical signs and symptoms of hypophosphatasia prior to age 18 years (e.g., respiratory insufficiency, vitamin B6 responsive seizures, hypotonia, failure to thrive, delayed walking, waddling gait, dental abnormalities, low trauma fractures)

OR

1.1.2 Radiographic evidence supporting the diagnosis of hypophosphatasia at the age of onset prior to age 18 years (e.g., craniosynostosis, infantile rickets, non-traumatic fractures)

AND

1.2 ONE of the following:

1.2.1 BOTH of the following:

1.2.1.1 Patient has low level activity of serum alkaline phosphatase (ALP) evidenced by an ALP level below the age and gender-adjusted normal range

AND

1.2.1.2 Patient has an elevated level of tissue non-specific alkaline phosphatase (TNSALP) substrate [e.g., serum pyridoxal 5'-phosphate (PLP) level, serum or urine phosphoethanolamine (PEA) level, urinary inorganic pyrophosphate (PPi level)]

OR

1.2.2 Confirmation of tissue-nonspecific alkaline phosphatase (TNSALP) gene mutation by ALPL genomic DNA (deoxyribonucleic acid) testing*

AND

2 - Prescribed by ONE of the following:

- Endocrinologist
- A specialist experienced in the treatment of metabolic bone disorders

AND

3 - ONE of the following:

3.1 BOTH of the following:

3.1.1 Diagnosis of perinatal/infantile-onset hypophosphatasia

AND

3.1.2 Request does not exceed a maximum supply limit of 9 mg/kg/week (milligrams/kilogram/week)

OR

3.2 BOTH of the following:

3.2.1 Diagnosis of juvenile-onset hypophosphatasia

AND

3.2.2 Request does not exceed a maximum supply limit of 6 mg/kg/week

AND

4 - ONE of the following:

4.1 Patient is prescribed Strensiq 18 mg/0.45 mL (milliliter), Strensiq 28 mg/0.7 mL, or Strensiq 40 mg/mL vials

OR

4.2 BOTH of the following:

4.2.1 Patient is prescribed Strensiq 80 mg/0.8 mL vial

AND

4.2.2 Patient's weight is greater than or equal to 40 kg

AND

5 - Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided

Notes	*Results of prior genetic testing can be submitted as confirmation of di agnosis of HPP, however please note that the provider should confirm coverage status of any new genetic testing under the patient's United Healthcare plan prior to ordering

Product Name: Strensiq	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Strensiq therapy (e.g., improvement in clinical symptoms, improvement in Radiographic Global Impression of Change)

AND

2 - Clinically relevant decrease from baseline in tissue non-specific alkaline phosphatase (TNSALP) substrate [e.g., serum pyridoxal 5'-phosphate (PLP) level, serum or urine phosphoethanolamine (PEA) level, urinary inorganic pyrophosphate (PPi level)]

AND

3 - Prescribed by ONE of the following:

- Endocrinologist
- A specialist experienced in the treatment of metabolic bone diseases

AND

4 - ONE of the following:

4.1 BOTH of the following:

4.1.1 Diagnosis of perinatal/infantile-onset hypophosphatasia

AND

4.1.2 Request does not exceed a maximum supply limit of 9 mg/kg/week (milligrams/kilogram/week)

OR

4.2 BOTH of the following:

4.2.1 Diagnosis of juvenile-onset hypophosphatasia

AND

4.2.2 Request does not exceed a maximum supply limit of 6 mg/kg/week

AND

5 - ONE of the following:

5.1 Patient is prescribed Strensiq 18 mg/0.45 mL (milliliter), Strensiq 28 mg/0.7 mL, or Strensiq 40 mg/mL vials

OR

5.2 BOTH of the following:

5.2.1 Patient is prescribed Strensiq 80 mg/0.8 mL vials

AND

5.2.2 Patient's weight is greater than or equal to 40 kg

AND

6 - Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided

Prior Authorization Guideline

GL-105930 Sutent

Formulary

Formulary Note

Guideline Note:

Effective Date:	6/1/2022

1 . Criteria

Product Name: Brand Sutent, generic sunitinib	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of gastrointestinal stromal tumor (GIST)	

AND

2 - History of failure, contraindication, or intolerance to imatinib (generic Gleevec)

Product Name: Brand Sutent, generic sunitinib	
Diagnosis	Renal Cell Carcinoma (RCC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of renal cell carcinoma (RCC)

AND

2 - ONE of the following:

2.1 Disease has relapsed

OR

2.2 Disease is advanced

OR

2.3 BOTH of the following:

2.3.1 Used in adjuvant setting

AND

2.3.2 Patient has a high risk of recurrence following nephrectomy

Product Name: Brand Sutent, generic sunitinib	
Diagnosis	Neuroendocrine and Adrenal Tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Progressive pancreatic neuroendocrine tumors (pNET)

AND

2 - Disease is ONE of the following:

- Unresectable, locally advanced
- Metastatic

Product Name: Brand Sutent, generic sunitinib	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Alveolar soft part sarcoma (ASPS)
- Angiosarcoma
- Solitary fibrous tumor/hemangiopericytoma

Product Name: Brand Sutent, generic sunitinib	
Diagnosis	Thyroid Carcinoma

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of ONE of the following:

- Follicular carcinoma
- Hürthle cell carcinoma
- Papillary carcinoma

AND

1.2 ONE of the following:

- Unresectable locoregional recurrent disease
- Persistent disease
- Metastatic disease

AND

1.3 ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

AND

1.4 Disease is refractory to radioactive iodine treatment

OR

2 - ALL of the following:

2.1 Diagnosis of medullary thyroid carcinoma

AND

2.2 ONE of the following:

- Patient has progressive disease
- Patient has symptomatic metastatic disease

AND

2.3 History of failure, contraindication, or intolerance to ONE of the following:

- Caprelsa (vandetanib)
- Cometriq (cabozantinib)

Product Name: Brand Sutent, generic sunitinib	
Diagnosis	Chordoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent chordoma

Product Name: Brand Sutent, generic sunitinib	
Diagnosis	Central Nervous System Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of surgically inaccessible meningiomas

AND

2 - ONE of the following:

- Disease is recurrent
- Disease is progressive

AND

3 - Further radiation is not possible

Product Name: Brand Sutent, generic sunitinib	
Diagnosis	Thymic Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of thymic carcinoma

AND

2 - Used as second-line following a failure, contraindication, or intolerance to a first-line chemotherapy regimen (e.g., carboplatin/paclitaxel)

Product Name: Brand Sutent, generic sunitinib	
Diagnosis	Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia

AND

2 - One of the following:

2.1 Patient has an FMS-like tyrosine kinase 3 (FLT3) rearrangement in chronic phase

OR

2.2 Treatment in combination with ALL (acute lymphocytic leukemia)- or AML (acute myeloid leukemia)-type induction chemotherapy followed by allogeneic HCT (hematopoietic cell transplantation) (if eligible) and FMS-like tyrosine kinase 3 (FLT3) rearrangement in blast phase

Product Name: Brand Sutent, generic sunitinib	
Diagnosis	GIST, RCC, Neuroendocrine and Adrenal Tumors, Soft Tissue Sarcoma, Thyroid Carcinoma, Chordoma, Central Nervous System Cancer, Thymic Carcinoma, Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Brand Sutent, generic sunitinib	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Brand Sutent, generic sunitinib	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Prior Authorization Guideline

GL-104288 Synagis

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/1/2022

1 . Criteria

Product Name: Synagis*	
Diagnosis	Prematurity
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Patient is an infant born before 29 weeks, 0 days gestation

AND

1.2 Patient is less than 12 months of age at the start of RSV "season"

AND

2 - Administered during RSV season**

AND

3 - Monthly dose of Synagis does not exceed 15 milligram per kilogram per dose

AND

4 - Monthly dose of Synagis does not exceed 5 doses per single RSV "season"***

AND

5 - The patient does not meet ONE of the following situations

- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with congenital heart disease and cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy
- Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the inability to clear secretions from the upper airway because of ineffective cough), or prematurity (less than 29 weeks, 0 days gestation) is present]
- Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present)
- Administration of monthly Synagis prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab
- Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children
- Synagis prophylaxis for prevention of nosocomial disease

• Treatment of symptomatic RSV disease	
Notes	*NOTE: Approval for up to 5 doses per single RSV “season” ** Information regarding RSV season may be found at: • Centers for Disease and Prevention (CDC) surveillance reports (http://www.cdc.gov/surveillance/nrevss/rsv/index.html) • http://uhc-cs-10.uhc.com/sites/cspm/CSSP/Pages/Synagis.aspx ***NOTE: Infants in a neonatal intensive care unit who qualify for prophylaxis may receive the first dose 48 to 72 hours before discharge to home or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose series for the season. And any subsequent doses received in the hospital setting, are also considered as part of the maximum 5 dose series. For infants born during the RSV “season,” fewer than 5 monthly doses may be needed.

Product Name: Synagis*	
Diagnosis	Chronic Lung Disease (CLD)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ALL of the following for patients age 0 to less than 12 months:

1.1.1 The patient is a preterm infant defined as gestational age less than 32 weeks, 0 days

AND

1.1.2 Patient has developed chronic lung disease (CLD) of prematurity

AND

1.1.3 There was a requirement for greater than 21% oxygen for at least the first 28 days after birth

OR

1.2 ALL of the following for patients age greater than or equal to 12 months to less than 24 months:

1.2.1 The patient was born at less than 32 weeks, 0 days gestation

AND

1.2.2 The patient required at least 28 days of oxygen after birth

AND

1.2.3 The patient continues to require supplemental oxygen, diuretics, or chronic systemic corticosteroid therapy within 6 months of the start of the second RSV “season”

AND

2 - Administered during RSV season**

AND

3 - Monthly dose of Synagis does not exceed 15 milligram per kilogram per dose

AND

4 - Monthly dose of Synagis does not exceed 5 doses per single RSV “season”***

AND

5 - The patient does not meet ONE of the following situations

- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with congenital heart disease and cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy

- Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the inability to clear secretions from the upper airway because of ineffective cough), or prematurity (less than 29 weeks, 0 days gestation) is present]
- Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present)
- Administration of monthly Synagis prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab
- Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children
- Synagis prophylaxis for prevention of nosocomial disease
- Treatment of symptomatic RSV disease

Notes	*NOTE: Approval for up to 5 doses per single RSV “season” ** Information regarding RSV season may be found at: • Centers for Disease and Prevention (CDC) surveillance reports (http://www.cdc.gov/surveillance/nrevss/rsv/index.html) • http://uhc-cs-10.uhc.com/sites/cspm/CSSP/Pages/Synagis.aspx ***NOTE: Infants in a neonatal intensive care unit who qualify for prophylaxis may receive the first dose 48 to 72 hours before discharge to home or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose series for the season. And any subsequent doses received in the hospital setting, are also considered as part of the maximum 5 dose series. For infants born during the RSV “season,” fewer than 5 monthly doses may be needed.

Product Name: Synagis*	
Diagnosis	Congenital Heart Disease (CHD)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ONE of the following for patients age 0 to less than 12 months:

1.1.1 Patient has hemodynamically significant congenital heart disease (CHD) including ONE of the following:

- Acyanotic heart disease and receiving medication to control congestive heart failure and will require cardiac surgical procedures
- Moderate to severe pulmonary hypertension

- Documentation that decisions regarding prophylaxis for infants with cyanotic heart defects were made in consultation with a pediatric cardiologist

OR

1.1.2 The patient is undergoing cardiac transplantation during the RSV “season”

OR

1.2 BOTH of the following:

1.2.1 The patient is greater than or equal to 12 months to less than 24 months of age:

AND

1.2.2 ONE of the following:

- After cardiac bypass
- At the conclusion of extracorporeal membrane oxygenation
- The patient is undergoing cardiac transplantation during the RSV “season”

AND

2 - Administered during RSV season**

AND

3 - Monthly dose of Synagis does not exceed 15 milligram per kilogram per dose

AND

4 - Monthly dose of Synagis does not exceed 5 doses per single RSV “season”***

AND

5 - The patient does not meet ONE of the following situations

- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with congenital heart disease and cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy
- Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the inability to clear secretions from the upper airway because of ineffective cough), or prematurity (less than 29 weeks, 0 days gestation) is present]
- Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present)
- Administration of monthly Synagis prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab
- Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children
- Synagis prophylaxis for prevention of nosocomial disease
- Treatment of symptomatic RSV disease

Notes	*NOTE: Approval for up to 5 doses per single RSV “season” ** Information regarding RSV season may be found at: • Centers for Disease and Prevention (CDC) surveillance reports (http://www.cdc.gov/surveillance/nrevss/rsv/index.html) • http://uhc-cs-10.uhc.com/sites/cspm/CSSP/Pages/Synagis.aspx ***NOTE: Infants in a neonatal intensive care unit who qualify for prophylaxis may receive the first dose 48 to 72 hours before discharge to home or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose series for the season. And any subsequent doses received in the hospital setting, are also considered as part of the maximum 5 dose series. For infants born during the RSV “season,” fewer than 5 monthly doses may be needed.

Product Name: Synagis*	
Diagnosis	Congenital abnormalities of the airway or neuromuscular disease
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Patient is age 0 to less than 12 months

AND

1.2 Patient has ONE of the following:

- Neuromuscular disease
- A congenital anomaly that impairs the ability to clear secretions from the lower airway because of ineffective cough

AND

2 - Administered during RSV season**

AND

3 - Monthly dose of Synagis does not exceed 15 milligram per kilogram per dose

AND

4 - Monthly dose of Synagis does not exceed 5 doses per single RSV "season"***

AND

5 - The patient does not meet ONE of the following situations

- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with congenital heart disease and cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy
- Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the inability to clear secretions from the upper airway because of ineffective cough), or prematurity (less than 29 weeks, 0 days gestation) is present]
- Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present)

• Administration of monthly Synagis prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab • Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children • Synagis prophylaxis for prevention of nosocomial disease • Treatment of symptomatic RSV disease	
Notes	*NOTE: Approval for up to 5 doses per single RSV “season” ** Information regarding RSV season may be found at: • Centers for Disease and Prevention (CDC) surveillance reports (http://www.cdc.gov/surveillance/nrevss/rsv/index.html) • http://uhc-cs-10.uhc.com/sites/cspm/CSSP/Pages/Synagis.aspx ***NOTE: Infants in a neonatal intensive care unit who qualify for prophylaxis may receive the first dose 48 to 72 hours before discharge to home or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose series for the season. And any subsequent doses received in the hospital setting, are also considered as part of the maximum 5 dose series. For infants born during the RSV “season,” fewer than 5 monthly doses may be needed.

Product Name: Synagis*	
Diagnosis	Immunocompromised children less than 24 months of age
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Patient is less than 24 months of age

AND

1.2 The patient is immunocompromised (e.g. receiving cancer chemotherapy, undergoing hematopoietic stem cell transplantation, or solid organ transplantation)

AND

2 - Administered during RSV season**

AND

3 - Monthly dose of Synagis does not exceed 15 milligram per kilogram per dose

AND

4 - Monthly dose of Synagis does not exceed 5 doses per single RSV “season”***

AND

5 - The patient does not meet ONE of the following situations

- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with congenital heart disease and cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy
- Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the inability to clear secretions from the upper airway because of ineffective cough), or prematurity (less than 29 weeks, 0 days gestation) is present]
- Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present)
- Administration of monthly Synagis prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab
- Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children
- Synagis prophylaxis for prevention of nosocomial disease
- Treatment of symptomatic RSV disease

Notes	*NOTE: Approval for up to 5 doses per single RSV “season” ** Information regarding RSV season may be found at: • Centers for Disease and Prevention (CDC) surveillance reports (http://www.cdc.gov/surveillance/nrevss/rsv/index.html) • http://uhc-cs-10.uhc.com/sites/cspm/CSSP/Pages/Synagis.aspx ***NOTE: Infants in a neonatal intensive care unit who qualify for prophylaxis may receive the first dose 48 to 72 hours before discharge to home or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose series for the season. And any subsequent doses received in the hospital setting, are also considered as p

	art of the maximum 5 dose series. For infants born during the RSV “se ason,” fewer than 5 monthly doses may be needed.

Product Name: Synagis*	
Diagnosis	Cystic fibrosis (CF)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following for patients age 0 to less than 12 months:

1.1.1 Patient has cystic fibrosis

AND

1.1.2 Patient has clinical evidence of at least ONE of the following:

- Chronic lung disease (CLD)
- Nutritional compromise
- Failure to thrive defined as weight for length less than the 10th percentile on a pediatric growth chart

OR

1.2 BOTH of the following:

1.2.1 Patient is greater than or equal to 12 months to less than 24 months of age

AND

1.2.2 Patient has manifestations of severe lung disease including ONE of the following:

- Previous hospitalization for pulmonary exacerbation in the first year of life
- Abnormalities on chest radiography or chest computed tomography that persists when stable
- Weight for length less than the 10th percentile on a pediatric growth chart

AND

2 - Administered during RSV season**

AND

3 - Monthly dose of Synagis does not exceed 15 milligram per kilogram per dose

AND

4 - Monthly dose of Synagis does not exceed 5 doses per single RSV “season”***

AND

5 - The patient does not meet ONE of the following situations

- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with congenital heart disease and cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy
- Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the inability to clear secretions from the upper airway because of ineffective cough), or prematurity (less than 29 weeks, 0 days gestation) is present]
- Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present)
- Administration of monthly Synagis prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab
- Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children
- Synagis prophylaxis for prevention of nosocomial disease
- Treatment of symptomatic RSV disease

Notes	*NOTE: Approval for up to 5 doses per single RSV “season” ** Information regarding RSV season may be found at: • Centers for Disease and Prevention (CDC) surveillance reports (http://www.cdc.gov/surveillance/nrevss/rsv/index.html) • http://uhc-cs-10.uhc.com/sites/cspm/CSSP/Pages/Synagis.aspx ***NOTE: Infants in a neonatal intensive care

	unit who qualify for prophylaxis may receive the first dose 48 to 72 hours before discharge to home or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose series for the season. And any subsequent doses received in the hospital setting, are also considered as part of the maximum 5 dose series. For infants born during the RSV "season," fewer than 5 monthly doses may be needed.

2 . Background

Benefit/Coverage/Program Information

Additional Information

In most of North America, peak RSV activity typically occurs between November and March, usually beginning in November or December, peaking in January or February, and ending by the end of March or sometime in April. Communities in the southern United States, particularly some communities in the state of Florida, tend to experience the earliest onset of RSV. Data from the Centers for Disease Control and Prevention (CDC) have identified variations in the onset and offset of the RSV "season" in the state of Florida that could affect the timing of Synagis administration. [10]

- Despite varied onsets, the RSV "season" is of the same duration (5 months) in the different regions of Florida.
- On the basis of the epidemiology of RSV in Alaska, particularly in remote regions where the burden of RSV disease is significantly greater than the general US population, the selection of Alaska Native infants eligible for prophylaxis may differ from the remainder of the United States. Clinicians may wish to use RSV surveillance data generated by the state of Alaska to assist in determining onset and end of the RSV season for qualifying infants.
- Limited information is available concerning the burden of RSV disease among Native American populations. However, special consideration may be prudent for Navajo and White Mountain Apache infants in the first year of life.

For analysis of National Respiratory and Enteric Virus Surveillance System (NREVSS) reports in the CDC Morbidity and Mortality Weekly Report, season onset is defined as the first of 2 consecutive weeks during which the mean percentage of specimens testing positive for RSV antigen is ≥ 10% or the mean percentage of specimens testing positive for RSV by PCR is ≥ 3%, whichever occurs first. RSV "season" offset is defined as the last week during which the mean percentage of positive specimens is ≥ 10%, or the mean percentage of positive specimens by PCR is ≥ 3%, whichever occurs last. Use of specimens to determine the start of the RSV "season" requires that the number of specimens tested be statistically significant.

3 . Revision History

Date	Notes
3/2/2022	Update

Prior Authorization Guideline

GL-100200 Synribo

Formulary

Formulary Note

Guideline Note:

Effective Date:	2/1/2022

1 . Criteria

Product Name: Synribo	
Diagnosis	Chronic Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of chronic or accelerated phase chronic myelogenous leukemia

OR

1.2 Diagnosis of advanced phase chronic myelogenous leukemia with progression to accelerated phase

OR

1.3 Patient has relapsed disease after hematopoietic stem cell transplant

AND

2 - Patient has a history of resistance and/or intolerance to TWO or more tyrosine kinase inhibitors [e.g., Gleevec (imatinib), Sprycel (dasatinib), Tasigna (nilotinib), Bosulif (bosutinib), Iclusig (ponatinib)]

Product Name: Synribo	
Diagnosis	Chronic Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Synribo therapy

Product Name: Synribo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Synribo will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Synribo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Synribo therapy

2 . Revision History

Date	Notes
12/14/2021	Copy NY

Prior Authorization Guideline

GL-90223 Tabrecta

Formulary

Formulary Note

Guideline Note:

Effective Date:	10/1/2021

1 . Criteria

Product Name: Tabrecta	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of non-small cell lung cancer (NSCLC)	

AND

2 - ONE of the following:

2.1 Presence of mesenchymal-epithelial transition (MET) exon 14 skipping positive tumors

OR

2.2 High level MET amplification in lung cancer

Product Name: Tabrecta	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tabrecta therapy

Product Name: Tabrecta	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Tabrecta will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Tabrecta

Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tabrecta therapy

2 . Revision History

Date	Notes
7/21/2021	Copy of NY GL-90207

Prior Authorization Guideline

GL-105994 Tafinlar

Formulary

Formulary Note

Guideline Note:

Effective Date:	6/1/2022

1 . Criteria

Product Name: Tafinlar	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Unresectable melanoma

OR

1.2 Metastatic melanoma

OR

1.3 BOTH of the following:

1.3.1 Prescribed as adjuvant therapy for melanoma involving the lymph node(s)

AND

1.3.2 Used in combination with Mekinist (trametinib)

AND

2 - Cancer is positive for BRAF V600 mutation

Product Name: Tafinlar	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

1.1.1 Patient has metastatic brain lesions

AND

1.1.2 Tafinlar is active against primary tumor (melanoma)

OR

1.2 BOTH of the following:

1.2.1 Patient has ONE of the following:

- Pilocytic astrocytoma
- Pleomorphic xanthoastrocytoma (PXA)
- Ganglioglioma

AND

1.2.2 Incomplete resection, biopsy, or surgically inaccessible location

OR

1.3 Patient has ONE of the following:

- Recurrent anaplastic glioma
- Recurrent glioblastoma
- Recurrent or progressive low-grade disease glioma

AND

2 - Cancer is positive for BRAF V600E mutation

AND

3 - Used in combination with Mekinist (trametinib)

Product Name: Tafinlar	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is ONE of the following:

- Metastatic
- Advanced
- Recurrent

AND

3 - Cancer is positive for BRAF V600E mutation

AND

4 - ONE of the following:

- Used in combination with Mekinist (trametinib)
- Used as a single agent if the combination of Mekinist and Tafinlar is not tolerated

Product Name: Tafinlar	
Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of anaplastic thyroid cancer (ATC)

AND

1.2 Cancer is positive for BRAF V600E mutation

AND

1.3 Used in combination with Mekinist (trametinib)

AND

1.4 ONE of the following:

1.4.1 Disease is ONE of the following:

- Metastatic
- Locally advanced
- Unresectable

OR

1.4.2 Prescribed as adjuvant therapy following resection

OR

2 - ALL of the following:

2.1 ONE of the following diagnoses:

- Follicular carcinoma
- Hürthle cell carcinoma
- Papillary carcinoma

AND

2.2 ONE of the following:

- Unresectable locoregional recurrent disease
- Persistent disease
- Metastatic disease

AND

2.3 ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

AND

2.4 Disease is refractory to radioactive iodine treatment

AND

2.5 Cancer is positive for BRAF V600 mutation

Product Name: Tafinlar	
Diagnosis	Hepatobiliary Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Gallbladder cancer
- Extrahepatic Cholangiocarcinoma
- Intrahepatic Cholangiocarcinoma

AND

2 - Used as subsequent treatment after progression on or after systemic treatment

AND

3 - Disease is unresectable or metastatic

AND

4 - Cancer is positive for BRAF V600E mutation

AND

5 - Used in combination with Mekinist (trametinib)

Product Name: Tafinlar	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Langerhans Cell Histiocytosis
- Erdheim-Chester Disease

AND

2 - Cancer is positive for BRAF V600E mutation

Product Name: Tafinlar	
Diagnosis	Melanoma, CNS Cancers, NSCLC, Thyroid Cancer, Hepatobiliary Cancers, Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tafinlar therapy

Product Name: Tafinlar	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Tafinlar	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tafinlar therapy

Prior Authorization Guideline

GL-100742 Tagrisso

Formulary

Formulary Note

Guideline Note:

Effective Date:	2/1/2022

1 . Criteria

Product Name: Tagrisso	
Diagnosis	Central Nervous System (CNS) Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of central nervous system (CNS) cancer	

AND

2 - Primary disease (tumor) is responsive to Tagrisso therapy [e.g., epidermal growth factor receptor (EGFR) T790M mutation, exon 19 deletions, or exon 21 L858R mutation-positive non-small cell lung cancer (NSCLC)]

Product Name: Tagrisso	
Diagnosis	Central Nervous System (CNS) Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tagrisso therapy

Product Name: Tagrisso	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is ONE of the following:

- Recurrent
- Advanced
- Metastatic

AND

3 - ONE of the following:

3.1 BOTH of the following:

3.1.1 Disease is sensitizing epidermal growth factor receptor (EGFR) mutation positive (e.g., EGFR T790M mutation, exon 19 deletions, or exon 21 L858R mutation-positive)

AND

3.1.2 Used as a first-line therapy

OR

3.2 BOTH of the following:

3.2.1 Disease is sensitizing EGFR mutation positive (e.g., EGFR T790M mutation, exon 19 deletions, or exon 21 L858R mutation-positive)

AND

3.2.2 Subsequent therapy for disease that has progressed while on Tagrisso therapy

OR

3.3 BOTH of the following:

3.3.1 Disease is EGFR T790M mutation-positive

AND

3.3.2 History of failure, contraindication, or intolerance to prior EGFR tyrosine kinase inhibitor (TKI) therapy [e.g., Tarceva (erlotinib), Gilotrif (afatinib), Iressa (gefitinib)]

OR

3.4 BOTH of the following:

3.4.1 Disease is EGFR exon 19 deletion or exon 21 L858R mutation positive

AND

3.4.2 Adjuvant therapy after tumor resection

Product Name: Tagrisso	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tagrisso therapy

Product Name: Tagrisso	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Tagrisso

Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tagrisso therapy

Prior Authorization Guideline

GL-106469 Talzenna

Formulary

Formulary Note

Guideline Note:

Effective Date:	7/1/2022

1 . Criteria

Product Name: Talzenna	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - Disease is ONE of the following:

- Locally advanced
- Metastatic

AND

3 - Presence of a germline BRCA (breast cancer)-mutation

AND

4 - ONE of the following:

4.1 Patient is currently on Talzenna therapy as confirmed by claims history or submitted medical records

OR

4.2 History of intolerance or contraindication to Lynparza (please specify intolerance or contraindication)

OR

4.3 Provider attests that the patient is not an appropriate candidate for Lynparza

Product Name: Talzenna	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Talzenna therapy

Product Name: Talzenna	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Talzenna	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Talzenna therapy

Prior Authorization Guideline

GL-99877 Tarceva

Formulary

Formulary Note

Guideline Note:

Effective Date:	2/1/2022

1 . Criteria

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Pancreatic Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of pancreatic cancer	

AND

2 - Disease is ONE of the following:

- Locally advanced
- Unresectable
- Metastatic

AND

3 - Used in combination with gemcitabine

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Pancreatic Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tarceva therapy

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is ONE of the following:

- Metastatic
- Recurrent

AND

3 - ONE of the following:

- Tumors are positive for epidermal growth factor receptor (EGFR)exon 19 deletions
- Tumors are positive for exon 21 (L858R) substitution mutations
- Tumors are positive for a known sensitizing EGFR mutation (e.g. in-frame exon 20 insertions, exon 18 G719 mutation, exon 21 L861Q mutation)

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tarceva therapy

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Chordoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chordoma

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Chordoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tarceva therapy

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Kidney Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

- Diagnosis of kidney cancer
- Disease is stage IV or relapsed

AND

2 - Disease is of non-clear cell histology

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Kidney Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tarceva therapy

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic brain cancer from Non-Small Cell Lung Cancer (NSCLC)

AND

2 - ONE of the following:

- Tumors are positive for epidermal growth factor receptor (EGFR) exon 19 deletions
- Tumors are positive for exon 21 (L858R) substitution mutations
- Tumors are positive for a known sensitizing EGFR mutation (e.g., in-frame exon 20 insertions, exon 18 G719 mutation, exon 21 L861Q mutation)

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tarceva therapy

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Vulvar cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of vulvar cancer

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Vulvar cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tarceva therapy

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Tarceva will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	NCCN Recommended Regimens

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tarceva therapy

2 . Revision History

Date	Notes
12/9/2021	Copy from NY

Prior Authorization Guideline

GL-78299 Tarceva

Formulary

Formulary Note

Guideline Note:

Effective Date:	2/1/2021

1 . Criteria

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Pancreatic Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of pancreatic cancer	

AND

2 - Disease is ONE of the following:

- Locally advanced
- Unresectable
- Metastatic

AND

3 - Used in combination with Gemzar (gemcitabine)

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Pancreatic Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tarceva therapy

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is ONE of the following:

- Metastatic
- Recurrent

AND

3 - ONE of the following:

- Tumors are positive for epidermal growth factor receptor (EGFR)exon 19 deletions
- Tumors are positive for exon 21 (L858R) substitution mutations
- Tumors are positive for a known sensitizing EGFR mutation (e.g. in-frame exon 20 insertions, exon 18 G719 mutation, exon 21 L861Q mutation)

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tarceva therapy

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Chordoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chordoma

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Chordoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tarceva therapy

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Kidney Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

- Diagnosis of kidney cancer
- Disease is stage IV or relapsed

AND

2 - Disease is of non-clear cell histology

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Kidney Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tarceva therapy

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic brain cancer from Non-Small Cell Lung Cancer (NSCLC)

AND

2 - ONE of the following:

- Tumors are positive for epidermal growth factor receptor (EGFR) exon 19 deletions
- Tumors are positive for exon 21 (L858R) substitution mutations
- Tumors are positive for a known sensitizing EGFR mutation (e.g., in-frame exon 20 insertions, exon 18 G719 mutation, exon 21 L861Q mutation)

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tarceva therapy

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Vulvar cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of vulvar cancer

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Vulvar cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tarceva therapy

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Tarceva will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	NCCN Recommended Regimens

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tarceva therapy

2 . Revision History

Date	Notes
12/15/2020	Minor change to kidney cancer section for clarity of intent. Added oth er EGFR sensitizing mutations to align with NSCLC section. Updated references.

Prior Authorization Guideline

GL-56578 Targretin

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2020
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Brand Targretin caps, generic bexarotene caps, Targretin gel	
Diagnosis	Cutaneous T-Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of cutaneous T-cell lymphoma (CTCL)

AND

2 - History of failure, contraindication, or intolerance to at least one prior therapy (including skin-directed therapies [e.g., corticosteroids (clobetasol, diflorasone, halobetasol, augmented betamethasone dipropionate), phototherapy, or systemic therapies [e.g. Interferons])

Product Name: Brand Targretin caps, generic bexarotene caps, Targretin gel	
Diagnosis	Cutaneous T-Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has not had disease progression while on therapy

Product Name: Brand Targretin caps, generic bexarotene caps, Targretin gel	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Targretin will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Product Name: Brand Targretin caps, generic bexarotene caps, Targretin gel	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Targretin therapy	

2 . Revision History

Date	Notes
11/6/2019	New Guideline.

Prior Authorization Guideline

GL-106482 Tarpeyo

Formulary

Formulary Note

Guideline Note:

Effective Date:	7/1/2022

1 . Criteria

Product Name: Tarpeyo	
Approval Length	9 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary immunoglobulin A nephropathy (IgAN)

AND

2 - Patient is at risk of rapid disease progression [e.g., generally a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g (gram), or by other criteria such as clinical risk scoring using the International IgAN Prediction Tool]

AND

3 - Used to reduce proteinuria

AND

4 - Estimated glomerular filtration rate (eGFR) greater than or equal to 35 mL/min/1.73 m^2 (milliliters/minute/1.73 square meters)

AND

5 - ONE of the following:

5.1 Patient is on a stabilized dose and receiving concomitant therapy with ONE of the following, as confirmed by claims history or submitted medical records:

- Maximally tolerated angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)
- Maximally tolerated angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)

OR

5.2 Patient has an allergy, contraindication, or intolerance to ACE inhibitors and ARB (please specify allergy, contraindication, or intolerance)

AND

6 - ONE of the following:

6.1 Failure of ONE glucocorticoid (e.g., methylprednisolone, prednisone) confirmed by claims history or submitted medical records

OR

6.2 History of intolerance or contraindication to ONE glucocorticoid (please specify intolerance or contraindication)

AND

7 - Prescribed by or in consultation with a nephrologist

Prior Authorization Guideline

GL-100976 Tasigna

Formulary

Formulary Note

Guideline Note:

Effective Date:	2/1/2022

1 . Criteria

Product Name: Tasigna	
Diagnosis	Chronic Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chronic myeloid leukemia	

AND

2 - ONE of the following:

2.1 Patient is not a candidate for imatinib (Gleevec) as attested by physician

OR

2.2 Patient is currently on Tasigna therapy

Product Name: Tasigna	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of progressive gastrointestinal stromal tumor (GIST)

AND

2 - History of failure, contraindication, or intolerance to ALL of the following:

- Gleevec (imatinib)
- Sutent (sunitinib)
- Stivarga (regorafenib)

Product Name: Tasigna	
Diagnosis	Acute Lymphoblastic Leukemia (Ph+B-ALL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Philadelphia chromosome-positive B-cell acute lymphoblastic leukemia (Ph+B-ALL)

Product Name: Tasigna	
Diagnosis	Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of myeloid/lymphoid neoplasms with eosinophilia and ABL1 (gene) rearrangement

AND

2 - Neoplasm is in blast or chronic phase

Product Name: Tasigna	
Diagnosis	Chronic Myeloid Leukemia, Gastrointestinal Stromal Tumor (GIST), Acute Lymphoblastic Leukemia (Ph+B-ALL), Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tasigna therapy

Product Name: Tasigna	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Tasigna will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Tasigna	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tasigna therapy

2 . Revision History

Date	Notes
12/22/2021	Copy NY

Prior Authorization Guideline

GL-62886 Tavalisse

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Tavalisse	
Diagnosis	Chronic immune thrombocytopenia (ITP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic immune thrombocytopenia (ITP)

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 History of failure, contraindication, or intolerance to ONE of the following:

- Corticosteroids
- Immunoglobulins

AND

2.1.2 History of failure, contraindication, or intolerance to Promacta (eltrombopag)

OR

2.2 Patient is currently on Tavalisse therapy

Product Name: Tavalisse	
Diagnosis	Chronic immune thrombocytopenia (ITP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tavalisse therapy

2 . Revision History

Date	Notes
3/10/2020	New Program

Prior Authorization Guideline

GL-102894 Tavneos

Formulary

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Tavneos	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of severe active ANCA-associated vasculitis	

AND

2 - Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting the disease is ONE of the following types:

2.1 Granulomatosis with polyangiitis (GPA)

OR

2.2 Microscopic polyangiitis (MPA)

AND

3 - Patient is being treated with an initial immunosuppressive regimen to induce remission (i.e., rituximab, cyclophosphamide)

AND

4 - Tavneos is being prescribed as adjunctive treatment in combination with standard therapy (e.g. prednisone, azathioprine, mycophenolate, methotrexate, rituximab, cyclophosphamide)

AND

5 - Prescribed by ONE of the following:

- Rheumatologist
- Nephrologist
- Pulmonologist
- Vascular Medicine Specialist

Product Name: Tavneos	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tavneos therapy

AND

2 - Tavneos is being prescribed as adjunctive treatment in combination with standard therapy (e.g. prednisone, azathioprine, mycophenolate, methotrexate, rituximab, cyclophosphamide)

AND

3 - Prescribed by, or in consultation with, ONE of the following:

- Rheumatologist
- Nephrologist
- Pulmonologist
- Vascular Medicine Specialist

2 . Revision History

Date	Notes
1/25/2022	New guideline

Prior Authorization Guideline

GL-106009 Tazverik

Formulary

Formulary Note

Guideline Note:

Effective Date:	6/1/2022

1 . Criteria

Product Name: Tazverik	
Diagnosis	Epithelioid Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has a diagnosis of epithelioid sarcoma	

AND

2 - Disease is ONE of the following:

- Metastatic
- Locally advanced

AND

3 - Disease is not eligible for complete resection

Product Name: Tazverik	
Diagnosis	Follicular Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of follicular lymphoma

AND

2 - Subsequent therapy for ONE of the following:

- EZH2 mutation positive relapsed/refractory disease after 2 prior therapies
- EZH2 wild-type or unknown relapsed/refractory disease and no satisfactory alternative treatment options

Product Name: Tazverik	
Diagnosis	Epithelioid Sarcoma, Follicular Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tazverik therapy

Product Name: Tazverik	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Tazverik	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tazverik therapy

Prior Authorization Guideline

GL-78483 Tegsedi

Formulary

Formulary Note

Guideline Note:

Effective Date:	2/1/2021

1 . Criteria

Product Name: Tegsedi	
Diagnosis	Hereditary transthyretin-mediated (hATTR) amyloidosis with polyneuropathy
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - BOTH of the following:	

- Diagnosis of Hereditary transthyretin-mediated (hATTR) amyloidosis with polyneuropathy
- Documentation that the patient has a pathogenic transthyretin (TTR) mutation (e.g., V30M)

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - Documentation of ONE of the following:

- Patient has a baseline polyneuropathy disability (PND) score less than or equal to IIIb
- Patient has a baseline familial amyloidotic polyneuropathy (FAP) Stage 1 or 2
- Patient has a baseline neuropathy impairment (NIS) score greater than or equal to 10 and less than or equal to 130

AND

4 - Patient has not had a liver transplant

AND

5 - Presence of clinical signs and symptoms of the disease (e.g., peripheral sensorimotor polyneuropathy, autonomic neuropathy, motor disability, etc.)

AND

6 - Patient is not receiving Tegsedi in combination with ONE of the following:

- Oligonucleotide agents [e.g., Onpattro (patisiran)]
- Tafamidis (e.g., Vyndaqel, Vyndamax)

Product Name: Tegsedi

Diagnosis	Hereditary transthyretin-mediated (hATTR) amyloidosis with polyneuropathy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has previously received treatment with Tegsedi

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - Documentation of ONE of the following:

- Patient continues to have a polyneuropathy disability (PND) score less than or equal to IIIb
- Patient continues to have a familial amyloidotic polyneuropathy (FAP) Stage 1 or 2
- Patient continues to have a neuropathy impairment (NIS) score greater than or equal to 10 and less than or equal to 130

AND

4 - Documentation that the patient has experienced a positive clinical response to Tegsedi therapy (e.g., improved neurologic impairment, motor function, quality of life, slowing of disease progression, etc.)

AND

5 - Patient is not receiving Tegsedi in combination with ONE of the following:

- Oligonucleotide agents [e.g., Onpattro (patisiran)]
- Tafamidis (e.g., Vyndaqel, Vyndamax)

2 . Revision History

Date	Notes
12/17/2020	Added examples of tafamidis products but no change to clinical inten t

Prior Authorization Guideline

GL-97960 Temodar

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: Brand Temodar, generic temozolomide	
Diagnosis	Central Nervous Systems (CNS) Tumor
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following types of central nervous system tumors:

- Intracranial and Spinal Ependymoma (excluding Subependymoma)

- Low-Grade Infiltrative Supratentorial Astrocytoma/Oligodendroglioma
- Medulloblastoma
- Anaplastic Gliomas
- Glioblastoma
- Limited or extensive brain metastases
- Primary CNS (central nervous system) lymphoma

Product Name: Brand Temodar, generic temozolomide	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following types of melanoma:

- Metastatic cutaneous melanoma
- Metastatic uveal melanoma
- Mucosal melanoma

Product Name: Brand Temodar, generic temozolomide	
Diagnosis	Neuroendocrine and Adrenal Tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following types of neuroendocrine tumors:

- Bronchopulmonary/thymic disease
- Poorly controlled carcinoid syndrome in lung or thymus
- Pancreas
- Pheochromocytoma/paraganglioma
- Poorly differentiated (High Grade)/ large or small cell

- Well differentiated grade 3 neuroendocrine tumors

Product Name: Brand Temodar, generic temozolomide	
Diagnosis	Primary Cutaneous Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following types of primary cutaneous lymphomas:

- Mycosis fungoides (MF)
- Sézary syndrome (SS)

Product Name: Brand Temodar, generic temozolomide	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

- Diagnosis of angiosarcoma
- Diagnosis of recurrent unresectable or stage IV retroperitoneal/intra-abdominal soft tissue sarcoma
- Diagnosis of rhabdomyosarcoma
- Undifferentiated pleomorphic sarcoma
- Diagnosis of solitary fibrous tumor/hemangiopericytoma

OR

2 - BOTH of the following:

2.1 Diagnosis of soft tissue sarcoma of the extremity/body wall, head/neck

AND

2.2 ONE of the following:

- Disease is stage IV
- Disease has disseminated metastases

Product Name: Brand Temodar, generic temozolomide	
Diagnosis	Bone Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Ewing's sarcoma family of tumors
- Mesenchymal chondrosarcoma

AND

2 - ONE of the following:

- Disease has relapsed
- Disease is progressive following primary treatment
- Used as second-line therapy for metastatic disease

AND

3 - Used in combination with Campostar (irinotecan)

Product Name: Brand Temodar, generic temozolomide	
Diagnosis	Uterine Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent or metastatic uterine sarcoma

Product Name: Brand Temodar, generic temozolomide	
Diagnosis	Small Cell Lung Cancer (SCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of small cell lung cancer (SCLC)

AND

2 - ONE of the following:

2.1 Relapse following complete or partial response or stable disease with primary treatment

OR

2.2 Primary progressive disease

Product Name: Brand Temodar, generic temozolomide	
Diagnosis	Central Nervous Systems (CNS) Tumor, Melanoma, Neuroendocrine and Adrenal Tumors, Primary Cutaneous Lymphomas, Soft Tissue Sarcoma, Bone Cancer, Uterine Sarcoma, Small Cell Lung Cancer (SCLC)

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Temodar therapy

Product Name: Brand Temodar, generic temozolomide	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Temodar will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Brand Temodar, generic temozolomide	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Temodar therapy

2 . Revision History

Date	Notes
11/4/2021	Update

Prior Authorization Guideline

GL-106492 Tepmetko

Formulary

Formulary Note

Guideline Note:

Effective Date:	7/1/2022

1 . Criteria

Product Name: Tepmetko	
Diagnosis	Non-Small Cell Lung Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of non-small cell lung cancer	

AND

2 - Disease is recurrent, advanced, or metastatic

AND

3 - Tumor is MET exon 14 skipping mutation positive

Product Name: Tepmetko	
Diagnosis	Non-Small Cell Lung Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tepmetko therapy

Product Name: Tepmetko	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Tepmetko	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tepmetko therapy

Prior Authorization Guideline

GL-108609 Test Strips

Formulary

Formulary Note

Guideline Note:

Effective Date:	8/1/2022

1 . Criteria

Product Name: Non-preferred Test Strips	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Failure of both of the following confirmed by claims history or submitted medical records:

- OneTouch Ultra Test Strips

- OneTouch Verio Test Strips

OR

1.2 History of intolerance or contraindication to both of the following (please specify intolerance or contraindication):

- OneTouch Ultra Test Strips
- OneTouch Verio Test Strips

OR

2 - Patient is on an insulin pump

Product Name: All Test Strips	
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - If the patient is insulin dependent or pregnant, the physician must confirm the patient requires a greater quantity because of more frequent blood glucose testing (e.g., patients on intravenous insulin infusions)

OR

2 - If the patient is not insulin dependent nor pregnant, ONE the following:

2.1 The patient is experiencing or is prone to hypoglycemia or hyperglycemia and requires additional testing to achieve glycemic control

OR

2.2 The patient's physician is adjusting medications and the patient requires additional blood glucose testing during this time

OR **2.3** The patient's physician is adjusting MNT (medical nutrition therapy) and the patient requires additional blood glucose testing during this time **OR** **2.4** The patient requires additional testing due to fluctuations in blood glucose due to physical activity/exercise **OR** **2.5** Other circumstances where prescribing physician confirms that the patient requires a greater quantity because of more frequent blood glucose testing (clinical review required by UnitedHealthcare reviewing pharmacist and/or medical director)	
Notes	The quantity limit for insulin-dependent and pregnant patients is 6 test strips/day. The quantity limit for non-insulin dependent and non-pregnant patients is 2 test strips/day.

2 . Revision History

Date	Notes
6/23/2022	Copy NY

Prior Authorization Guideline

GL-108834 Thalomid

Formulary

Formulary Note

Guideline Note:

Effective Date:	8/1/2022

1 . Criteria

Product Name: Thalomid	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of multiple myeloma	

Product Name: Thalomid	
Diagnosis	Erythema Nodosum Leprosum (ENL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe erythema nodosum leprosum (ENL)

AND

2 - ONE of the following:

2.1 Used for acute treatment

OR

2.2 Used as maintenance therapy for prevention & suppression of cutaneous manifestations of ENL recurrence

Product Name: Thalomid	
Diagnosis	B-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Castleman's Disease (CD)

AND

2 - ONE of the following:

2.1 NOT used as first line therapy

OR

2.2 ALL of the following:

- Therapy is for active idiopathic multicentric CD with no evidence of organ failure
- Used in combination with cyclophosphamide and prednisone
- Patient is human immunodeficiency virus (HIV)-negative
- Patient is human herpesvirus-8 (HHV8)-negative

Product Name: Thalomid	
Diagnosis	Myelofibrosis-Associated Anemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary myelofibrosis

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Serum erythropoietin levels less than 500 mU/mL (milliunits/milliliter)

AND

2.1.2 ONE of the following:

- Failure to erythropoietins [e.g., Procrit (epoetin alfa)] as confirmed by claims history or submission of medical records

- History of contraindication or intolerance to erythropoietins [e.g., Procrit (epoetin alfa)] (please specify contraindication or intolerance)

OR

2.2 Serum erythropoietin levels greater than or equal to 500 mU/mL

Product Name: Thalomid	
Diagnosis	Myelofibrosis-Associated Anemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation that the patient has evidence of symptom improvement or reduction in spleen/liver volume while on Thalomid

Product Name: Thalomid	
Diagnosis	Kaposi Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of HIV (human immunodeficiency virus)-negative Kaposi Sarcoma

OR

1.2 BOTH of the following:

1.2.1 Diagnosis of AIDS-related Kaposi Sarcoma

AND

1.2.2 Patient is currently being treated with antiretroviral therapy (ART) as confirmed by claims history or submission of medical records

AND

2 - Not used as first line therapy

Product Name: Thalomid	
Diagnosis	Langerhans Cell Histiocytosis, Rosai-Dorfman Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Langerhans cell histiocytosis

OR

2 - Diagnosis of Rosai-Dorfman Disease

Product Name: Thalomid	
Diagnosis	Multiple Myeloma, B-Cell Lymphomas, Kaposi Sarcoma, Langerhans Cell Histiocytosis, Rosai-Dorfman Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Thalomid therapy

Product Name: Thalomid	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	

Product Name: Thalomid	
Diagnosis	Erythema Nodosum Leprosum (ENL), NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Thalomid therapy	

2 . Revision History

Date	Notes
6/29/2022	Removed off-label criteria (aphthous stomatitis or ulcer, pyoderma gangrenosum, and cutaneous manifestations systemic lupus erythematosus). Updated B-cell lymphoma and Kaposi sarcoma criteria per NCCN guidance. Updated trial/failure language throughout policy.

Prior Authorization Guideline

GL-97052 Tibsovo

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: Tibsovo	
Diagnosis	Acute Myeloid Leukemia (AML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - AML is IDH1 (isocitrate dehydrogenase 1) mutation-positive

AND

3 - ONE of the following:

- Disease is relapsed or refractory
- Patient is greater than or equal to 60 years old
- Patient has comorbidities that preclude the use of intensive induction chemotherapy
- Patient is receiving Tibsovo as post-induction therapy following response to previous lower intensity therapy with the same regimen

Product Name: Tibsovo	
Diagnosis	Chondrosarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chondrosarcoma

AND

2 - Susceptible IDH1 (isocitrate dehydrogenase 1) mutation-positive

AND

3 - Disease is ONE of the following:

- Conventional (grades 1-3)

- Dedifferentiated

Product Name: Tibsovo	
Diagnosis	Cholangiocarcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cholangiocarcinoma

AND

2 - Susceptible IDH1 (isocitrate dehydrogenase 1) mutation-positive

AND

3 - Disease is ONE of the following:

- Locally advanced
- Unresectable
- Metastatic

AND

4 - Disease has progressed on or after systemic treatment

Product Name: Tibsovo	
Diagnosis	Acute Myeloid Leukemia (AML), Chondrosarcoma, Cholangiocarcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tibsovo therapy

Product Name: Tibsovo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Tibsovo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tibsovo therapy

2 . Revision History

Date	Notes
10/21/2021	Update

Prior Authorization Guideline

GL-101733 Topical Agents - Corticosteroids

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/11/2022

1 . Criteria

Product Name: generic alclometasone, Apexicon-E cream, generic betamethasone dipropionate, generic calcipotriene/betamethasone dipropionate (all formulations except oint), Brand Taclonex, Brand Wynzora, Brand Enstilar, Bryhali, Brand Clobex, Clodan, Brand Cloderm, generic clocortolone, Brand Cordran, Nolix, generic DesRx, generic desonide, Brand Topicort, generic desoximetasone, generic fluocinolone (oil, cream, ointment), Brand Dermotic, Brand Synalar, generic Flac, generic halobetasol propionate, Lexette, generic hydrocortisone butyrate, Brand Locoid, generic hydrocortisone valerate, Brand Halog, generic halcinonide, Brand Kenalog, Brand Luxiq, generic betamethasone valerate foam, Brand Olux, Brand Olux-E, Tovet, Brand Pandel, Brand Sernivo, Brand Temovate, Brand Desowen, Brand Tridesilon, Brand Psorcon, generic Beser, generic fluticasone lotion, Brand Cutivate, Brands of hydrocortisone cream and lotion and ointment, Brand Trianex, Impeklo, Brand Diprolene AF, Brand Diprolene, generic augmented betamethasone dipropionate, generic fluocinonide 0.1%, Brand Vanos	
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has failed therapeutic trials of 14 days with TWO preferred medications*

OR

2 - ONE of the following:

- Patient has an allergy to at least TWO preferred medications*
- Patient has a contraindication to ALL preferred medications*
- Patient has a history of unacceptable/toxic side effects to at least TWO preferred medications*

Notes	Length of authorization: 365 days for low and medium potency, 90 da ys for high and very high potency. See Background for potency exam ples (not all inclusive) *PDL link: https://www.uhcprovider.com/en/heal th-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharm acy.html

2 . Background

Benefit/Coverage/Program Information

Table 1: Low Potency

Desowen (desonide) cream, ointment, lotion	Carmol HC (hydrocortisone with urea) cream
Synalar (fluocinolone acetonide) 0.01% cream, solution	Pandel (hydrocortisone probutate) cream
Derma-Smoothe/FS (fluocinolone) body oil, scalp oil	Pediaderm HC kit
hydrocortisone cream, lotion, ointment, gel	Capex (fluocinolone acetonide) shampoo
Aclovate (alclometasone) cream, ointment	Desonate (desonide) gel

Table 2: Medium Potency

betamethasone dipropionate-calcipotriene ointment	Cloderm (clocortolone pivalate)

Valisone (betamethasone valerate) cream, lotion	Cordran (flurandrenolide)
Cutivate (fluticasone propionate) cream, ointment, lotion	Topicort (desoximetasone) cream, gel, ointment
Elocon (mometasone furoate) cream, ointment, solution	Synalar (fluocinolone acetonide) 0.025% cream, ointment
Dermatop (prednicarbate) cream, ointment	Locoid (hydrocortisone butyrate) cream, ointment, solution
Aristocort, Kenalog (triamcinolone acetonide) cream, ointment, lotion	Westcort (hydrocortisone valerate) cream, ointment
Diprolene (betamethasone dipropionate) lotion	Luxiq (betamethasone valerate) foam

Table 3: High Potency

amcinonide ointment, cream, lotion	Diprolene (betamethasone dipropionate) cream, ointment
Valisone (betamethasone valerate) ointment	Vanos (fluocinonide) cream
Florone (diflorasone diacetate) cream, ointment	Halog (halcinonide) cream, ointment
Lidex, Lidex-E (fluocinonide) cream, gel, ointment, solution	Kenalog (triamcinolone acetonide) aerosol spray
Apexicon-E (diflorasone diacetate) emollient base	Sernivo (betamethasone dipropionate) spray

Table 4: Very High Potency

Clobex, Olux, Olux-E,Temovate (clobetasol propionate) cream, foam, gel, lotion, ointment, spray, shampoo, solution	Clodan (clobetasol propionate) shampoo, kit
Diprolene AF (betamethasone dipropionate augmented) cream, ointment, lotion, gel	Ultravate (halobetasol propionate) cream, ointment
Bryhali (halobetasol propionate) lotion	Lexette (halobetasol propionate) foam

3 . Revision History

Date	Notes
1/11/2022	Updated Product list.

Prior Authorization Guideline

GL-107378 Topical Agents- Immunomodulators

Formulary

Formulary Note

Guideline Note:

Effective Date:	7/1/2022

1 . Criteria

Product Name: Brand Elidel, generic tacrolimus	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - The patient is 2 years of age or older

AND

2 - ONE of the following:

2.1 Patient has had an inadequate clinical response to TWO 30-day trials of topical corticosteroids

OR

2.2 One of the following:

- Topical corticosteroids are deemed inadvisable because of potential risks
- Intolerance to topical corticosteroids

Product Name: Brand Protopic, Eucrisa, generic pimecrolimus, Opzelura	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient has had an inadequate clinical response to preferred alternatives, including a 30-day trial of a preferred product *

OR

1.2 Patient cannot be changed to a preferred medication due to ONE of the following:

1.2.1 Patient has an allergy to preferred medications

OR

1.2.2 Patient has a contraindication to, or drug interaction with, preferred medications

OR

1.2.3 Patient has a history of unacceptable/toxic side effects to preferred medications **AND** **2** - If the request is for generic pimecrolimus or Brand Protopic, the patient is 2 years of age or older

Notes	* PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
5/20/2022	Updated Brand Protopic and generic tacrolimus based on 7.1.22 UP DL changes.

Prior Authorization Guideline

GL-57116 Topical Agents: Anti-Fungals

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2020

1 . Criteria

Product Name: Ciclopirox Nail Lacquer Kit*, Brand Penlac*, Ertaczo*, Exelderm Cream*, Exelderm Solution*, Jublia*, Kerydin*, Brand Extina*, generic ketoconazole foam*, Brand Luzu*, generic luliconazole cream*, Mentax*, Brand Naftin cream*, generic naftifine cream*, Brand Naftin Gel*, generic naftifine gel*, Brand Oxistat cream*, generic oxiconazole cream*, Oxistat lotion*, Vusion*, miconazole-zinc oxide-white petrolatum ointment*	
Approval Length	Duration of the prescription (up to 180 days)
Guideline Type	Prior Authorization
Approval Criteria **1** - The patient has failed therapeutic trials of 14 days with TWO preferred medications**	

OR **2** - The infection is caused by, or presumed to be caused by, an organism resistant to preferred medications **OR** **3** - Patient cannot be changed to a preferred medication due to ONE of the following: **3.1** Patient has an allergy to TWO preferred medications **OR** **3.2** Patient has a contraindication to ALL preferred medications **OR** **3.3** Patient has a history of unacceptable/toxic side effects to TWO preferred medications

Notes	*NOTE: Length of authorization should be the duration of the prescription (up to 180 days) **NOTE PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
11/20/2019	C&S Implementation

Prior Authorization Guideline

GL-107486 Topical Agents: Anti-Parasitics

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/26/2022

1 . Criteria

Product Name: Crotan lotion, Brand Ovide lotion, generic malathion lotion, spinosad suspension, Brand Sklice lotion, generic ivermectin lotion	
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient cannot be changed to a medication not requiring prior approval due to ONE of the following: *

1.1.1 Patient has an allergy to medications not requiring prior approval

OR

1.1.2 Patient has a contraindication to, or drug interaction with, medications not requiring prior approval

OR

1.1.3 Patient has a history of unacceptable/toxic side effects to medications not requiring prior approval

OR

1.2 Patient has had a therapeutic failure to a 30 day trial of one medication not requiring prior approval *

OR

1.3 The requested medication's corresponding generic (if covered by the state) has been attempted and failed or is contraindicated

AND

2 - The requested medication is being used for an indication as approved by the FDA**

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html?rfid=UHCCP **Indications Approved By The FDA: • Benzyl alcohol lotion is indicated for patients 6 months of age and older • Crotamiton is indicated for adults • Ivermectin is indicated for age 6 months and older • Lindane lotion and shampoo are indicated only in patients who cannot tolerate or who have failed other treatments. The P&T Committee does not recommend use of lindane. • Malathion is indicated for patients 6 years of age and older • Permethrin cream and lotion are indicated for patients 2 months of age and older • Spinosad is indicated for patients 6 months of age and older Package labeling does not list age for permethrin or piperonyl butoxode-pyrethrins

2 . Revision History

Date	Notes
5/26/2022	Removed Eurax, no longer active. Added generic Sklice. Added Cort an and Ovide.

Prior Authorization Guideline

GL-90131 Truseltiq

Formulary

Formulary Note

Guideline Note:

Effective Date:	10/1/2021

1 . Criteria

Product Name: Truseltiq	
Diagnosis	Cholangiocarcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of cholangiocarcinoma	

AND

2 - Disease is ONE of the following:

- Unresectable locally advanced
- Metastatic

AND

3 - Disease has presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement

AND

4 - Patient has been previously treated

Product Name: Truseltiq	
Diagnosis	Cholangiocarcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Truseltiq therapy

Product Name: Truseltiq	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Truseltiq	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Truseltiq therapy

Prior Authorization Guideline

GL-100805 Tukysa

Formulary

Formulary Note

Guideline Note:

Effective Date:	2/1/2022

1 . Criteria

Product Name: Tukysa	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - Disease is ONE of the following:

- Advanced unresectable
- Metastatic

AND

3 - Disease is human epidermal growth factor receptor 2 (HER2)-positive

AND

4 - Patient has been previously treated with an anti-HER2-based regimen in the metastatic setting [e.g., trastuzumab (Herceptin, Kanjinti), pertuzumab (Perjeta), ado-trastuzumab emtansine (T-DM1)]

AND

5 - Used in combination with trastuzumab (e.g., Herceptin, Kanjinti, Ontruzant) and capecitabine (Xeloda)

Product Name: Tukysa	
Diagnosis	CNS Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of brain metastases with HER2 (human epidermal growth factor receptor 2) positive breast cancer

AND

2 - Patient has been previously treated with an anti-HER2-based regimen [e.g., trastuzumab (Herceptin, Kanjinti), pertuzumab (Perjeta), ado-trastuzumab emtansine (T-DM1)]

AND

3 - Used in combination with trastuzumab (e.g., Herceptin, Kanjinti, Ontruzant) and capecitabine (Xeloda)

Product Name: Tukysa	
Diagnosis	Breast Cancer, CNS Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tukysa therapy

Product Name: Tukysa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Tukysa

Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tukysa therapy

Prior Authorization Guideline

GL-97078 Turalio

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: Turalio	
Diagnosis	Tenosynovial Giant Cell Tumor (TGCT)/Pigmented Villonodular Synovitis (PVNS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has a diagnosis of tenosynovial giant cell tumor (TGCT)/pigmented villonodular synovitis (PVNS)	

Product Name: Turalio	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Langerhans Cell Histiocytosis
- Erdheim-Chester Disease
- Rosai-Dorfman Disease

AND

2 - Colony stimulating factor 1 receptor (CSF1R) mutation positive

Product Name: Turalio	
Diagnosis	Tenosynovial Giant Cell Tumor (TGCT)/Pigmented Villonodular Synovitis (PVNS), Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Turalio therapy

Product Name: Turalio	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Turalio	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Turalio therapy

Prior Authorization Guideline

GL-97100 Tykerb

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: Brand Tykerb, generic lapatinib	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - BOTH of the following:	

1.1 Diagnosis of recurrent or stage IV hormone receptor positive, human epidermal growth factor receptor 2-positive (HER2+) breast cancer

AND

1.2 Used in combination with an aromatase inhibitor [e.g., Aromasin (exemestane), Femara (letrozole), Arimidex (anastrozole)]

OR

2 - BOTH of the following:

2.1 Diagnosis of advanced or stage IV HER2+ breast cancer

AND

2.2 Used in combination with ONE of the following:

- Herceptin (trastuzumab)
- Xeloda (capecitabine)

Product Name: Brand Tykerb, generic lapatinib	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of recurrent, central nervous system (CNS) cancer with metastatic lesions

AND

1.2 Tykerb is active against primary (breast) tumor

AND

1.3 Used in combination with Xeloda (capecitabine)

OR

2 - ALL of the following:

2.1 Diagnosis of recurrent intracranial or spinal ependymoma (excluding subependymoma)

AND

2.2 Patient has received previous radiation therapy

AND

2.3 Patient has received ONE of the following:

- Gross total or subtotal resection
- Localized recurrence
- Evidence of metastasis (brain, spine, or cerebral spinal fluid)

AND

2.4 Used in combination with Temodar (temozolomide)

Product Name: Brand Tykerb, generic lapatinib	
Diagnosis	Chordoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of epidermal growth factor receptor (EGFR)-positive, recurrent chordoma

Product Name: Brand Tykerb, generic lapatinib	
Diagnosis	Colon Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of unresectable, advanced, or metastatic colon cancer [human epidermal growth factor receptor 2 (HER2)-amplified and RAS wild type]

AND

2 - Patient has not previously been treated with a HER2 inhibitor [e.g., Kanjinti (trastuzumab), Perjeta (pertuzumab), Nerlynx (neratinib)]

AND

3 - Patient has previously been treated with ONE of the following regimens:

- Oxaliplatin-based therapy without irinotecan
- Irinotecan-based therapy without oxaliplatin
- FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, and irinotecan) regimen
- A fluoropyrimidine without irinotecan or oxaliplatin

AND

4 - Used in combination with trastuzumab

Product Name: Brand Tykerb, generic lapatinib

Diagnosis	Rectal Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of unresectable, advanced, or metastatic rectal cancer [human epidermal growth factor receptor 2 (HER2)-amplified and RAS and BRAF wild type]

AND

2 - Patient has not previously been treated with a HER2 inhibitor [e.g., Kanjinti (trastuzumab), Perjeta (pertuzumab), Nerlynx (neratinib)]

AND

3 - Used in combination with trastuzumab

AND

4 - ONE of the following:

4.1 Patient has previously been treated with ONE of the following regimens:

- Oxaliplatin-based therapy without irinotecan
- Irinotecan-based therapy without oxaliplatin
- FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, and irinotecan) regimen
- A fluoropyrimidine without irinotecan or oxaliplatin

OR

4.2 Intensive therapy is not appropriate for the patient

Product Name: Brand Tykerb, generic lapatinib

Diagnosis	Breast Cancer, Central Nervous System (CNS) Cancers, Chordoma, Colon Cancer, Rectal Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tykerb therapy

Product Name: Brand Tykerb, generic lapatinib	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Tykerb will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Brand Tykerb, generic lapatinib	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tykerb therapy

Prior Authorization Guideline

GL-86205 Ukoniq

Formulary

Formulary Note

Guideline Note:

Effective Date:	7/1/2021

1 . Criteria

Product Name: Ukoniq	
Diagnosis	Marginal Zone Lymphoma/Follicular Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of marginal zone lymphoma

AND

1.2 Disease is relapsed or refractory

AND

1.3 Patient has received at least one prior anti-CD20-based regimen [e.g., Rituxan (rituximab), Gazyva (obinutuzumab)]

OR

2 - ALL of the following:

2.1 Diagnosis of follicular lymphoma

AND

2.2 Disease is relapsed or refractory

AND

2.3 Patient has received at least three prior lines of systemic therapy

Product Name: Ukoniq	
Diagnosis	Marginal Zone Lymphoma/Follicular Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Ukoniq therapy

Product Name: Ukoniq	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Ukoniq	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Ukoniq therapy

Prior Authorization Guideline

GL-80099 Upneeq

Formulary

Formulary Note

Guideline Note:

Effective Date:	3/1/2021

1 . Criteria

Product Name: Upneeq	
Diagnosis	Acquired Blepharoptosis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acquired blepharoptosis

AND

2 - Patient has a functional impairment related to the position of the eyelid

AND

3 - ONE of the following:

3.1 Marginal reflex distance-1 (MRD-1) is less than or equal to 2 millimeters (mm) in primary gaze

OR

3.2 Marginal reflex distance-1 (MRD-1) is less than or equal to 2 mm in down gaze

OR

3.3 Superior visual field loss of at least 12 degrees or 24 percent

AND

4 - Other treatable causes of blepharoptosis have been ruled out (e.g., recent botulinum toxin injections, myasthenia gravis)

Product Name: Upneeq	
Diagnosis	Acquired Blepharoptosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy

2 . Revision History

Date	Notes
1/26/2021	Copy of NY-79983 New Program

Prior Authorization Guideline

GL-97115 Valchlor

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: Valchlor	
Diagnosis	Primary Cutaneous Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Chronic or smoldering T-cell leukemia/lymphoma

- Primary cutaneous marginal zone or follicle center B-cell lymphoma
- Lymphomatoid papulosis (LyP) with extensive lesions
- Mycosis fungoides (MF)/Sezary syndrome (SS)

Product Name: Valchlor	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Langerhans Cell Histiocytosis (LCH)

AND

2 - Skin disease is unifocal and isolated

Product Name: Valchlor	
Diagnosis	Primary Cutaneous Lymphomas, Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Valchlor

Product Name: Valchlor	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Valchlor	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Valchlor therapy

Prior Authorization Guideline

GL-106283 Vancomycin

Formulary

Formulary Note

Guideline Note:

Effective Date:	7/1/2022

1 . Criteria

Product Name: Brand Firvanq, generic vancomycin oral solution, Brand Vancocin	
Diagnosis	Clostridioides difficile-associated diarrhea (CDAD) [previously known as Clostridium difficile-associated diarrhea]
Approval Length	10 Day(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Clostridioides difficile-associated diarrhea (CDAD) [previously known as Clostridium difficile-associated diarrhea]	

AND

2 - The prescriber provides a reason or special circumstance the patient cannot use generic vancomycin capsules* (document reason why patient is unable to use generic vancomycin capsules)

Notes	*Generic vancomycin capsules are preferred. Brand Vancocin capsules, generic vancomycin oral solution, and Brand Firvanq oral solution are non-preferred.

Product Name: Brand Firvanq, generic vancomycin oral solution, Brand Vancocin	
Diagnosis	Clostridioides difficile-associated diarrhea (CDAD) [previously known as Clostridium difficile-associated diarrhea]
Approval Length	12 Week(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Recurrence of Clostridioides difficile infection [previously known as Clostridium difficile-associated diarrhea] after prior treatment with oral vancomycin

AND

2 - The prescriber provides a reason or special circumstance the patient cannot use generic vancomycin capsules* (document reason why patient is unable to use generic vancomycin capsules)

Notes	*Generic vancomycin capsules are preferred. Brand Vancocin capsules, generic vancomycin oral solution, and Brand Firvanq oral solution are non-preferred.

Product Name: Brand Firvanq, generic vancomycin oral solution, Brand Vancocin	
Diagnosis	Staphylococcal Enterocolitis
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of enterocolitis due to Staphylococcus aureus

AND

2 - The prescriber provides a reason or special circumstance the patient cannot use generic vancomycin capsules* (document reason why patient is unable to use generic vancomycin capsules)

Notes	*Generic vancomycin capsules are preferred. Brand Vancocin capsules, generic vancomycin oral solution, and Brand Firvanq oral solution are non-preferred.

2 . Revision History

Date	Notes
4/18/2022	Updated all criteria and notes for new step therapy language. Updated auth duration for staph enterocolitis.

Prior Authorization Guideline

GL-62956 Vecamyl

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Vecamyl	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of moderately severe to severe essential hypertension

OR **1.2** Diagnosis of uncomplicated malignant hypertension

Product Name: Vecamyl	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of a positive clinical response to Vecamyl therapy	

2 . Revision History

Date	Notes
3/12/2020	2020 Implementation

Prior Authorization Guideline

GL-76834 Vemlidy

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2021

1 . Criteria

Product Name: Vemlidy	
Diagnosis	Treatment-Naïve Chronic Hepatitis B Infection
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Patient has a contraindication to entecavir therapy

Product Name: Vemlidy

Diagnosis	Treatment-Experienced Chronic Hepatitis B Infection
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - ONE of the following:

1.1 Patient has a history of failure, intolerance, or contraindication to entecavir therapy

OR

1.2 BOTH of the following:

1.2.1 Patient is currently on Viread therapy

AND

1.2.2 ONE of the following:

1.2.2.1 Patient has a creatinine clearance less than 60 mL per minute

OR

1.2.2.2 Patient has a diagnosis of osteoporosis

OR

1.3 Patient is currently on Vemlidy therapy

Prior Authorization Guideline

GL-106617 Venclexta

Formulary

Formulary Note

Guideline Note:

Effective Date:	7/1/2022

1 . Criteria

Product Name: Venclexta	
Diagnosis	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)	

Product Name: Venclexta	
Diagnosis	Mantle Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of mantle cell lymphoma (MCL)

AND

2 - Not used as first line therapy

Product Name: Venclexta	
Diagnosis	Acute Myeloid Leukemia (AML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Newly-diagnosed acute myeloid leukemia (AML)

AND

1.2 Venclexta therapy to be given in combination with ONE of the following:

- Azacitidine
- Decitabine
- Low-dose cytarabine

AND

1.3 ONE of the following:

- Patient is greater than or equal to 60 years old
- Patient has significant comorbidities that preclude the use of intensive induction chemotherapy

OR

2 - ALL of the following:

2.1 Diagnosis of relapsed/refractory acute myeloid leukemia (AML)

AND

2.2 Relapse is greater than or equal to 12 months from most recent disease remission

AND

2.3 Venclexta therapy to be given in combination with the patient's previous initial successful induction regimen (e.g., azacitidine, decitabine, low-dose cytarabine, etc.)

Product Name: Venclexta	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of relapsed or progressive multiple myeloma which has been previously treated

AND

2 - Used in combination with dexamethasone

AND

3 - Patient has t(11;14) translocation

Product Name: Venclexta	
Diagnosis	Acute Lymphoblastic Leukemia (ALL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of relapsed/refractory acute lymphoblastic leukemia (ALL)

AND

2 - Venclexta therapy to be given in combination with ONE of the following:

- Decitabine
- Hyper-CVAD
- Nelarabine
- Mini hyper-CVD

Product Name: Venclexta	
Diagnosis	Systemic Light Chain Amyloidosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of relapsed/refractory systemic light chain amyloidosis

AND

2 - Patient has t(11;14) translocation

Product Name: Venclexta	
Diagnosis	Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma which has been previously treated

Product Name: Venclexta	
Diagnosis	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL), Mantle Cell Lymphoma, Acute Myeloid Leukemia (AML), Multiple Myeloma, Acute Lymphoblastic Leukemia (ALL), Systemic Light Chain Amyloidosis, Waldenstrom Macroglobulinemia/Lymphoplasmac
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Venclexta therapy

Product Name: Venclexta	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Venclexta will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Venclexta	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Venclexta therapy

2 . Revision History

Date	Notes
4/27/2022	Updated criteria to include acute lymphoblastic leukemia, systemic light chain amyloidosis, and Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma based on NCCN recommendations.

Prior Authorization Guideline

GL-109467 Verkazia

Formulary

Formulary Note

Guideline Note:

Effective Date:	8/1/2022

1 . Criteria

Product Name: Verkazia, Cyclosporine in Klarity	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe vernal keratoconjunctivitis

AND

2 - ONE of the following:

2.1 Failure to TWO of the following categories as confirmed by claims history or submission of medical records:

- Ophthalmic antihistamines (e.g., azelastine, olopatadine)
- Ophthalmic mast cell stabilizers (e.g., cromolyn sodium)
- Ophthalmic corticosteroids (e.g., dexamethasone, prednisolone, fluorometholone)

OR

2.2 History of intolerance or contraindication to ALL of the following categories (please specify intolerance or contraindication)

- Ophthalmic antihistamines (e.g., azelastine, olopatadine)
- Ophthalmic mast cell stabilizers (e.g., cromolyn sodium)
- Ophthalmic corticosteroids (e.g., dexamethasone, prednisolone, fluorometholone)

Product Name: Verkazia, Cyclosporine in Klarity	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response

2 . Revision History

Date	Notes
7/15/2022	New guideline

Prior Authorization Guideline

GL-104661 Verzenio

Formulary

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Verzenio	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - Disease is hormone-receptor (HR)-positive

AND

3 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

4 - ONE of the following:

4.1 BOTH of the following:

4.1.1 Disease is advanced, recurrent, or metastatic

AND

4.1.2 ONE of the following:

4.1.2.1 Used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane) or Faslodex (fulvestrant)

OR

4.1.2.2 ALL of the following:

- Used as monotherapy
- Patient has disease progression following endocrine therapy
- Patient has already received at least one prior chemotherapy regimen

OR

4.2 BOTH of the following:

4.2.1 Disease is early breast cancer at high risk of recurrence (i.e., greater than or equal to

4 positive lymph nodes, or 1-3 positive lymph nodes with one or more of the following: Grade 3 disease, tumor size greater than or equal to 5 centimeters, or a Ki-67 score greater than or equal to 20 percent)

AND

4.2.2 Used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane) or tamoxifen

Product Name: Verzenio	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Verzenio therapy

Product Name: Verzenio	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Verzenio will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Verzenio	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Verzenio therapy	

2 . Revision History

Date	Notes
3/14/2022	Updated OR to AND between steps 4.2.1; 4.2.2

Prior Authorization Guideline

GL-109300 Vijoice

Formulary

Formulary Note

Guideline Note:

Effective Date:	9/1/2022

1 . Criteria

Product Name: Vijoice	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of PIK3CA-Related Overgrowth Spectrum (PROS) based on all of the following criteria

1.1 Confirmed presence of a mutation in the PIK3CA gene

AND

1.2 Patient is 2 years of age or older

AND

1.3 ONE of the following:

1.3.1 TWO or more of the following spectrum features

- Overgrowth: adipose, muscle, nerve, skeletal
- Vascular malformations: capillary, venous, arteriovenous, lymphatic
- Epidermal nevus

OR

1.3.2 ONE or more of the following isolated features:

- Large isolated lymphatic malformation
- Isolated macrodactyly or overgrown splayed feet/ hands with overgrown limbs
- Truncal adipose overgrowth
- Hemimegalencephaly (bilateral) / dysplastic megalencephaly / focal cortical dysplasia
- Epidermal nevus
- Seborrheic keratoses
- Benign lichenoid keratoses

AND

2 - Patient has severe manifestations of PROS (e.g., severe vascular malformations, chronic gastrointestinal bleeding, severe dyspnea, disabling chronic pain, severe epilepsy, severe manifestations despite previous debulking surgery)

AND

3 - Prescribed by, or in consultation with, a clinical geneticist or a practitioner who has specialized expertise in the management of PROS manifestations

Product Name: Vijoice	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Vijoice therapy

AND

2 - Prescribed by, or in consultation with, a clinical geneticist or a practitioner who has specialized expertise in the management of PIK3CA-Related Overgrowth Spectrum (PROS) manifestations.

2 . Revision History

Date	Notes
7/12/2022	New guideline.

Prior Authorization Guideline

GL-103510 Vitrakvi

Formulary

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Vitrakvi	
Diagnosis	Solid Tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Presence of a solid tumor

AND

2 - Disease is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion (e.g. ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

3 - Disease is without a known acquired resistance mutation (e.g., TRKA G595R, G623R, G696A, F617L)

AND

4 - Disease is ONE of the following:

- Metastatic
- Unresectable

AND

5 - ONE of the following:

- Disease has progressed on previous treatment (e.g., surgery, radiotherapy, or systemic therapy)
- Disease has no satisfactory alternative treatments

Product Name: Vitrakvi	
Diagnosis	Solid tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Vitrakvi therapy

Product Name: Vitrakvi	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Vitrakvi will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Vitrakvi	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Vitrakvi therapy

2 . Revision History

Date	Notes
2/9/2022	Update

Prior Authorization Guideline

GL-100902 Vizimpro

Formulary

Formulary Note

Guideline Note:

Effective Date:	2/1/2022

1 . Criteria

Product Name: Vizimpro	
Diagnosis	Non-small cell lung cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of non-small cell lung cancer (NSCLC)	

AND

2 - Disease is recurrent, advanced or metastatic

AND

3 - Disease is positive for ONE of the following EGFR (epidermal growth factor receptor) mutations:

- Exon 19 deletion
- Exon 21 L858R substitution

Product Name: Vizimpro	
Diagnosis	Non-small cell lung cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Vizimpro therapy

Product Name: Vizimpro	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Vizimpro will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Vizimpro	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Vizimpro therapy	

2 . Revision History

Date	Notes
12/20/2021	Updated criteria for Non-small lung cancer. Updated GPIs for Vizimpro

Prior Authorization Guideline

GL-108822 Vonjo

Formulary

Formulary Note

Guideline Note:

Effective Date:	8/1/2022

1 . Criteria

Product Name: Vonjo	
Diagnosis	Myelofibrosis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Primary myelofibrosis

- Post-polycythemia vera myelofibrosis
- Post-essential thrombocythemia myelofibrosis

AND

2 - Patient has a platelet count below 50 x 10^9/L

Product Name: Vonjo	
Diagnosis	Myelofribrosis
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation that patient has evidence of symptom improvement or reduction in spleen volume while on Vonjo

Product Name: Vonjo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Vonjo will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Vonjo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Vonjo therapy

Prior Authorization Guideline

GL-78526 Votrient

Formulary

Formulary Note

Guideline Note:

Effective Date:	2/1/2021

1 . Criteria

Product Name: Votrient	
Diagnosis	Renal Cell Carcinoma (RCC)/Kidney Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of renal cell carcinoma (RCC)	

AND

2 - ONE of the following:

- Disease is relapsed
- Stage IV disease

Product Name: Votrient	
Diagnosis	Soft Tissue Sarcoma (STS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of ONE of the following:

- Angiosarcoma
- Alveolar soft part sarcoma
- Pleomorphic rhabdomyosarcoma
- Retroperitoneal/Intra-abdominal disease that is unresectable or progressive
- Soft tissue sarcoma of the extremity/superficial trunk or head/neck with disease that is stage IV or recurrent and has disseminated metastases
- Solitary fibrous tumor/hemangiopericytoma

OR

1.2 BOTH of the following:

1.2.1 Diagnosis of progressive gastrointestinal stromal tumors (GIST)

AND

1.2.2 History of failure, contraindication, or intolerance to ALL of the following:

- Gleevec (imatinib)
- Sutent (sunitinib)
- Stivarga (regorafenib)

Product Name: Votrient	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 ALL of the following:

1.1.1 Diagnosis of ONE of the following:

- Follicular carcinoma
- Hürthle cell carcinoma
- Papillary carcinoma

AND

1.1.2 ONE of the following:

- Unresectable locoregional recurrent disease
- Persistent disease
- Metastatic disease

AND

1.1.3 ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

AND

1.1.4 ONE of the following:

- Disease is refractory to radioactive iodine treatment
- Distant metastatic disease not amenable to radioactive iodine treatment

OR

1.2 ALL of the following:

1.2.1 Diagnosis of medullary carcinoma

AND

1.2.2 ONE of the following:

- Disease is progressive
- Disease is symptomatic with distant metastases

AND

1.2.3 History of failure, contraindication, or intolerance to ONE of the following:

- Caprelsa (vandetanib)
- Cometriq (cabozantinib)

Product Name: Votrient	
Diagnosis	Uterine Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of uterine sarcoma

AND

2 - One of the following:

- Disease is recurrent
- Disease is metastatic

AND

3 - Disease has progressed following previous cytotoxic chemotherapy (e.g., doxorubicin, docetaxel/gemcitabine, etc.)

Product Name: Votrient	
Diagnosis	Ovarian Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Epithelial ovarian cancer
- Fallopian tube cancer
- Primary peritoneal cancer

AND

2 - ONE of the following:

- Disease is persistent
- Disease is recurrent

Product Name: Votrient	
Diagnosis	Renal Cell Carcinoma (RCC)/Kidney Cancer, Soft Tissue Sarcoma (STS), Thyroid Carcinoma, Uterine Sarcoma, Ovarian Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Votrient therapy

Product Name: Votrient	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Votrient will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Votrient	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Votrient therapy

Prior Authorization Guideline

GL-106039 Voxzogo

Formulary

Formulary Note

Guideline Note:

Effective Date:	6/1/2022

1 . Criteria

Product Name: Voxzogo	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Patient is at least 5 years of age

AND

1.2 Patient is less than 18 years of age

AND

2 - Diagnosis of achondroplasia as confirmed by ONE of the following:

2.1 Submission of medical records documenting BOTH of the following:

2.1.1 Patient has clinical manifestations characteristic of achondroplasia (e.g., macrocephaly, frontal bossing, midface retrusion, disproportionate short stature with rhizomelic shortening of the arms and the legs, brachydactyly, trident configuration of the hands, thoracolumbar kyphosis, and accentuated lumbar lordosis)

AND

2.1.2 Patient has radiographic findings characteristic of achondroplasia (e.g., large calvaria and narrowing of the foramen magnum region, undertubulated, shortened long bones with metaphyseal abnormalities, narrowing of the interpedicular distance of the caudal spine, square ilia and horizontal acetabula, small sacrosciatic notches, proximal scooping of the femoral metaphyses, and short and narrow chest)

OR

2.2 Submission of medical records documenting molecular genetic testing confirmed c.1138G > A or c.1138G > C variant (i.e., p.Gly380Arg mutation) in the fibroblast growth factor receptor-3 (FGFR3) gene

AND

3 - Patient has open epiphyses

AND

4 - BOTH of the following:

4.1 Patient has not had limb-lengthening surgery in the previous 18 months

AND

4.2 Patient does not plan to have limb-lengthening surgery while on Voxzogo

AND

5 - Prescribed by ONE of the following:

- Clinical geneticist
- Endocrinologist
- A practitioner who has specialized expertise in the management of achondroplasia

Product Name: Voxzogo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Voxzogo therapy [e.g., improvement in annualized growth velocity (AGV) compared to baseline]

AND

2 - Patient continues to have open epiphyses

AND

3 - Patient does not plan to have limb-lengthening surgery while on Voxzogo

AND

4 - Prescribed by or in consultation with ONE of the following:

- Clinical geneticist
- Endocrinologist
- A practitioner who has specialized expertise in the management of achondroplasia

Prior Authorization Guideline

GL-106954 Vuity

Formulary

Formulary Note

Guideline Note:

Effective Date:	7/1/2022

1 . Criteria

Product Name: Vuity	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of presbyopia	

AND

2 - Patient is between the ages of 40 to 55

AND

3 - Documentation of the medical rationale for why patient is unable to use corrective lenses (e.g., glasses, contacts)

AND

4 - Prescribed by one of the following:

- Optometrist
- Ophthalmologist

Product Name: Vuity	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Age less than 55

AND

3 - Prescribed by ONE of the following:

- Optometrist
- Ophthalmologist

2 . Revision History

Date	Notes
5/5/2022	New Criteria

Prior Authorization Guideline

GL-62897 Vyndaqel and Vyndamax

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Vyndaqel, Vyndamax	
Diagnosis	Transthyretin (ATTR)-mediated amyloidosis with cardiomyopathy (ATTR-CM)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of transthyretin (ATTR)-mediated amyloidosis with cardiomyopathy (ATTR-CM)	

AND

2 - ONE of the following:

2.1 Documentation that the patient has a pathogenic transthyretin (TTR) mutation (e.g., V30M)

OR

2.2 Cardiac or noncardiac tissue biopsy demonstrating histologic confirmation of ATTR amyloid deposits

OR

2.3 ALL of the following:

2.3.1 Echocardiogram or cardiac magnetic resonance imaging suggestive of amyloidosis

AND

2.3.2 Radionuclide imaging (99mTc-DPD, 99mTc-PYP, or 99m Tc-HMDP) showing grade 2 or 3 cardiac uptake*

AND

2.3.3 Absence of monoclonal protein identified in serum, urine immunofixation (IFE), serum free light chain (sFLC) assay

AND

3 - Prescribed by, or in consultation, with a cardiologist

AND

4 - Presence of clinical signs and symptoms of cardiomyopathy (e.g., heart failure, dyspnea, edema, hepatomegaly, ascites, angina, etc.)

AND

5 - Documentation of BOTH of the following:

5.1 ONE of the following:

5.1.1 Patient has New York Heart Association (NYHA) Functional Class I or II heart failure

OR

5.1.2 BOTH of the following:

5.1.2.1 Patient has New York Heart Association (NYHA) Functional Class III heart failure

AND

5.1.2.2 Patient's cardiopulmonary functional status allows patient to ambulate 100 meters or greater in six minutes or less

AND

5.2 Patient has an N-terminal pro-B-type naturetic peptide (NT-proBNP) level greater than or equal to 600 picograms/milliliter

AND

6 - ONE of the following:

6.1 Patient is not receiving Vyndaqel/Vyndamax in combination with one of the following:

- Onpattro (patisiran)
- Tegsedi (inotersen)

OR

6.2 If the patient is receiving Vyndaqel/Vyndamax in combination with Onpattro (patisiran) or Tegsedi (inotersen), the physician attests that he/she will coordinate care with other specialist(s) involved in the patient's amyloidosis treatment plan to determine optimal long term monotherapy** treatment regimen

Notes	*May require prior authorization and notification ** Referring to monot herapy with Vyndaqel/Vyndamax, Onpattro, or Tegsedi

Product Name: Vyndaqel, Vyndamax	
Diagnosis	Transthyretin (ATTR)-mediated amyloidosis with cardiomyopathy (ATTR-CM)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation that the patient has experienced a positive clinical response to Vyndaqel or Vyndamax (e.g., improved symptoms, quality of life, slowing of disease progression, decreased hospitalizations, etc.)

AND

2 - Prescribed by or in consultation with a cardiologist

AND

3 - Documentation that patient continues to have New York Heart Association (NYHA) Functional Class I, II, or III heart failure

AND

4 - Patient is not receiving Vyndaqel/Vyndamax in combination with one of the following:

- Onpattro (patisiran)
- Tegsedi (inotersen)

2 . Revision History

Date	Notes
3/26/2020	New Program

Prior Authorization Guideline

GL-97053 Welireg

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: Welireg	
Diagnosis	Von Hippel-Lindau (VHL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Von Hippel-Lindau (VHL) disease

AND

2 - Patient requires therapy for one of the following:

- Renal cell carcinoma (RCC)
- Central nervous system (CNS) hemangioblastoma
- Pancreatic neuroendocrine tumor (pNET)

AND

3 - Patient does not require immediate surgery

Product Name: Welireg	
Diagnosis	Von Hippel-Lindau (VHL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of disease progression while on Welireg

Product Name: Welireg	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Welireg will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Welireg	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Welireg therapy

2 . Revision History

Date	Notes
10/21/2021	Copy NY

Prior Authorization Guideline

GL-105119 Xalkori

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/1/2022

1 . Criteria

Product Name: Xalkori	
Diagnosis	Inflammatory Myofibroblastic Tumor (IMT)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of inflammatory myofibroblastic tumor (IMT) with anaplastic lymphoma kinase (ALK) translocation

Product Name: Xalkori	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is ONE of the following:

- Metastatic
- Recurrent
- Advanced

AND

3 - ONE of the following:

- Tumor is anaplastic lymphoma kinase (ALK)-positive
- Tumor is ROS1-positive
- Tumor is positive for mesenchymal-epithelial transition (MET) amplification
- Tumor is positive for MET exon 14 skipping mutation

Product Name: Xalkori	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic brain cancer from non-small cell lung cancer (NSCLC)

AND

2 - ONE of the following:

- Tumor is anaplastic lymphoma kinase (ALK)-positive
- Tumor is ROS1-positive

Product Name: Xalkori	
Diagnosis	Anaplastic Large Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anaplastic large cell lymphoma

AND

2 - Tumor is anaplastic lymphoma kinase (ALK)-positive

AND

3 - Disease is relapsed or refractory

Product Name: Xalkori	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Langerhans Cell Histiocytosis
- Erdheim-Chester Disease
- Rosai-Dorfman Disease

AND

2 - Disease is positive for anaplastic lymphoma kinase (ALK) rearrangement

Product Name: Xalkori	
Diagnosis	Inflammatory Myofibroblastic Tumor (IMT), Non-Small Cell Lung Cancer (NSCLC), Central Nervous System (CNS) Cancers, Anaplastic Large Cell Lymphoma, Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Xalkori therapy

Product Name: Xalkori	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Xalkori will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Xalkori	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xalkori therapy

2 . Revision History

Date	Notes
3/23/2022	Copy NY

Prior Authorization Guideline

GL-60332 Xenleta

Formulary

Formulary Note

Guideline Note:

Effective Date:	4/1/2020

1 . Criteria

Product Name: Xenleta	
Diagnosis	Community-acquired bacterial pneumonia
Approval Length	7 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 For continuation of therapy upon hospital discharge

OR

1.2 As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR

1.3 All of the following:

1.3.1 Diagnosis of community-acquired bacterial pneumonia (CABP)

AND

1.3.2 Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Xenleta

AND

1.3.3 History of failure, contraindication, or intolerance to three of the following antibiotics:

- Amoxicillin
- A macrolide
- Doxycycline
- A fluoroquinolone
- Combination therapy with amoxicillin/clavulanate or cephalosporin AND a macrolide or doxycycline

Product Name: Xenleta*	
Diagnosis	Off-Label Uses
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 For continuation of therapy upon hospital discharge **OR** **1.2** As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication **OR** **1.3** The drug has been recognized for treatment of the indication by the Infectious Diseases Society of America (IDSA)	
Notes	*Approval Duration: Based on provider and IDSA recommended treatment durations, not to exceed 6 months

2 . Revision History

Date	Notes
1/31/2020	New Program

Prior Authorization Guideline

GL-109322 Xermelo

Formulary

Formulary Note

Guideline Note:

Effective Date:	9/1/2022

1 . Criteria

Product Name: Xermelo	
Diagnosis	Carcinoid Syndrome Diarrhea
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of carcinoid syndrome diarrhea

AND

2 - Diarrhea is inadequately controlled with somatostatin analog therapy (e.g., octreotide, Sandostatin LAR, Somatuline Depot), as confirmed by claims history or submission of medical records

AND

3 - Used in combination with somatostatin analog therapy (e.g., octreotide, Sandostatin LAR, Somatuline Depot)

Product Name: Xermelo	
Diagnosis	Carcinoid Syndrome Diarrhea
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xermelo

Prior Authorization Guideline

GL-104240 Xifaxan

Formulary

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Xifaxan	
Diagnosis	Hepatic Encephalopathy
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria **1** - Diagnosis of hepatic encephalopathy	

AND

2 - Patient has had therapeutic failure (defined as a recurrent episode) while on lactulose

Notes	* PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html

Product Name: Xifaxan	
Diagnosis	Irritable Bowel Syndrome (IBS)
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Patient has had an inadequate clinical response to a preferred* medication

OR

2 - One of the following

- Allergy to preferred medications
- Contraindication to or drug interaction to preferred medications
- History of unacceptable/toxic side effects to preferred medications

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html

Product Name: Xifaxan	
Diagnosis	All other diagnosis
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Patient is 18 years of age or older

AND

2 - One of the following

2.1 Patient has had an inadequate clinical response to a 14-day trial of TWO preferred* medications

OR

2.2 Patient has ONE of the following:

- Allergy to preferred medications
- Contraindication to or drug interaction to preferred medications
- History of unacceptable/toxic side effects to preferred medications

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html

2 . Revision History

Date	Notes
3/2/2022	New Guideline

Prior Authorization Guideline

GL-101929 Xospata

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/14/2022

1 . Criteria

Product Name: Xospata	
Diagnosis	Acute Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - AML is FMS-like tyrosine kinase 3 (FLT3) mutation-positive

AND

3 - Disease is relapsed or refractory

Product Name: Xospata	
Diagnosis	Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia

AND

2 - ONE of the following:

2.1 Patient has an FMS-like tyrosine kinase 3 (FLT3) rearrangement in chronic phase

OR

2.2 Treatment in combination with acute lymphoblastic leukemia (ALL)- or acute myeloid leukemia (AML)-type induction chemotherapy followed by allogeneic HCT (if eligible) and FMS-like tyrosine kinase 3 (FLT3) rearrangement in blast phase

Product Name: Xospata	
Diagnosis	Acute Myeloid Leukemia, Myeloid/Lymphoid Neoplasms

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Xospata therapy

Product Name: Xospata	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Xospata will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Xospata	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xospata therapy

2 . Revision History

Date	Notes
1/14/2022	Update

Prior Authorization Guideline

GL-103388 Xpovio

Formulary

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Xpovio	
Diagnosis	Multiple myeloma- Request for Xpovio PLUS dexamethasone
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of relapsed or refractory multiple myeloma (RRMM)	

AND

2 - Patient has received at least four prior therapies

AND

3 - Disease is refractory to all of the following:

- Two proteasome inhibitors
- Two immunomodulatory agents
- An anti-CD38 monoclonal antibody

AND

4 - Xpovio will be used in combination with dexamethasone

Product Name: Xpovio	
Diagnosis	Multiple myeloma- Request for Xpovio PLUS dexamethasone PLUS [Darzalex(daratumumab) or Velcade (bortezomib)]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple myeloma

AND

2 - Patient has received at least one prior therapy

AND

3 - Xpovio will be used in combination with ONE of the following

- Velcade (bortezomib) plus dexamethasone
- Darzalex (daratumumab) plus dexamethasone

Product Name: Xpovio	
Diagnosis	Multiple myeloma- Request for Xpovio PLUS dexamethasone PLUS Pomalyst (pomalidomide)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple myeloma

AND

2 - Xpovio will be used in combination with Pomalyst (pomalidomide) and dexamethasone

AND

3 - Patient has received at least 2 prior therapies, including an immunomodulatory agent (e.g., lenalidomide, thalidomide) and a proteasome inhibitor (e.g., bortezomib, carfilzomib)

AND

4 - Patient has demonstrated progression on or within 60 days of completion of the last therapy

Product Name: Xpovio	
Diagnosis	Diffuse Large B-cell Lymphoma (DLBCL)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of relapsed or refractory diffuse large B-cell lymphoma (DLBCL) (including DLBCL arising from follicular lymphoma)

AND

2 - Patient has received at least 2 lines of systemic therapies

Product Name: Xpovio	
Diagnosis	Multiple Myeloma (all regimens), Diffuse Large B-cell Lymphoma (DLBCL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Xpovio therapy

Product Name: Xpovio	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Xpovio	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xpovio therapy

2 . Revision History

Date	Notes
2/4/2022	Copy NY

Prior Authorization Guideline

GL-106047 Xtandi

Formulary

Formulary Note

Guideline Note:

Effective Date:	6/1/2022

1 . Criteria

Product Name: Xtandi	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of prostate cancer	

AND

2 - ONE of the following:

2.1 Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

OR

2.2 Patient has had bilateral orchiectomy

AND

3 - ONE of the following:

3.1 If the disease is metastatic, castration-resistant, ONE of the following:

3.1.1 History of failure, contraindication, or intolerance to Zytiga

OR

3.1.2 Continuation of ongoing Xtandi therapy

OR

3.2 If the disease is non-metastatic, castration-resistant, ONE of the following:

3.2.1 History of failure, contraindication, or intolerance to BOTH of the following:

- Erleada (apalutamide)
- Nubeqa (darolutamide)

OR

3.2.2 Continuation of ongoing Xtandi therapy

OR

3.3 If the disease is metastatic, castration-sensitive, ONE of the following:

3.3.1 History of failure, contraindication, or intolerance to BOTH of the following:

- Erleada (apalutamide)
- abiraterone (generic Zytiga)

OR

3.3.2 Continuation of ongoing Xtandi therapy

Product Name: Xtandi	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Xtandi therapy

Product Name: Xtandi	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Xtandi	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xtandi therapy

Prior Authorization Guideline

GL-62902 Xuriden

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Xuriden	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of a hereditary orotic aciduria

Product Name: Xuriden

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xuriden therapy

2 . Revision History

Date	Notes
3/5/2020	New Program

Prior Authorization Guideline

GL-106068 Yonsa

Formulary

Formulary Note

Guideline Note:

Effective Date:	6/1/2022

1 . Criteria

Product Name: Yonsa	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of prostate cancer	

AND

2 - ONE of the following:

2.1 Disease is metastatic

OR

2.2 Disease is regional node positive (e.g., N1)

OR

2.3 Patient is in a very-high-risk group receiving external beam radiation therapy (EBRT)

AND

3 - Used in combination with methylprednisolone

AND

4 - ONE of the following:

4.1 Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

OR

4.2 Patient has had bilateral orchiectomy

AND

5 - ONE of the following:

5.1 Prescriber provides a reason or special circumstance the patient cannot take abiraterone (generic Zytiga)

OR

5.2 Patient is currently on Yonsa therapy

Product Name: Yonsa	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Yonsa therapy

Product Name: Yonsa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Yonsa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Yonsa therapy

Prior Authorization Guideline

GL-109368 Zejula

Formulary

Formulary Note

Guideline Note:

Effective Date:	9/1/2022

1 . Criteria

Product Name: Zejula	
Diagnosis	Ovarian Cancer (Maintenance Therapy)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Recurrent or advanced epithelial ovarian cancer

- Recurrent or advanced fallopian tube cancer
- Recurrent or advanced primary peritoneal cancer

AND

2 - Patient is in a complete or partial response to a platinum-based chemotherapy

AND

3 - Request is for maintenance therapy

Product Name: Zejula	
Diagnosis	Ovarian Cancer (Treatment)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced, persistent, or recurrent ovarian, fallopian tube, or primary peritoneal cancer

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 Patient has been treated with three or more prior chemotherapy regimens

AND

2.1.2 Patient's cancer is associated with homologous recombination deficiency (HRD) positive status defined by ONE of the following:

2.1.2.1 Presence of deleterious or suspected deleterious BRCA (breast cancer) mutation

OR

2.1.2.2 BOTH of the following:

2.1.2.2.1 Genomic instability

AND

2.1.2.2.2 Cancer has progressed more than 6 months after response to the last platinum-based chemotherapy (e.g., cisplatin, carboplatin)

OR

2.2 BOTH of the following:

2.2.1 Disease is platinum-sensitive

AND

2.2.2 Used in combination with bevacizumab

Product Name: Zejula	
Diagnosis	Uterine Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of BRCA (breast cancer) altered uterine leiomyosarcoma (uLMS)

AND

2 - Disease has progressed following prior treatment with ONE of the following:

- gemcitabine plus docetaxel
- doxorubicin

Product Name: Zejula	
Diagnosis	Ovarian Cancer (Maintenance Therapy, Treatment), Uterine Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Zejula therapy

Product Name: Zejula	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Zejula	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Zejula therapy

Prior Authorization Guideline

GL-106085 Zelboraf

Formulary

Formulary Note

Guideline Note:

Effective Date:	6/1/2022

1 . Criteria

Product Name: Zelboraf	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Unresectable melanoma

- Metastatic melanoma

AND

2 - Patient is positive for BRAF V600 mutation

Product Name: Zelboraf	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

- Patient has metastatic brain lesions
- Zelboraf is active against primary tumor (melanoma)

OR

1.2 BOTH of the following:

1.2.1 Patient has ONE of the following:

- Pilocytic astrocytoma
- Pleomorphic xanthoastrocytoma (PXA)
- Ganglioglioma

AND

1.2.2 Incomplete resection, biopsy, or surgically inaccessible location

AND

2 - Cancer is positive for BRAF V600E mutation

AND

3 - Used in combination with Cotellic (cobimetinib)

Product Name: Zelboraf	
Diagnosis	Hairy Cell Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hairy cell leukemia

Product Name: Zelboraf	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is ONE of the following:

- Metastatic
- Advanced
- Recurrent

AND

3 - Cancer is positive for BRAF V600E mutation

Product Name: Zelboraf	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Erdheim-Chester Disease
- Langerhans Cell Histiocytosis

AND

2 - Cancer is positive for BRAF V600 mutation

Product Name: Zelboraf	
Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Follicular carcinoma
- Hürthle cell carcinoma
- Papillary carcinoma

AND

2 - ONE of the following:

- Unresectable locoregional recurrent disease
- Metastatic disease
- Persistent disease

AND

3 - ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

AND

4 - Disease is refractory to radioactive iodine

AND

5 - Cancer is positive for BRAF V600 mutation

Product Name: Zelboraf	
Diagnosis	Melanoma, CNS Cancers, Hairy Cell Leukemia, NSCLC, Histiocytic Neoplasms, Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Zelboraf therapy

Product Name: Zelboraf	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Zelboraf	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Zelboraf therapy

Prior Authorization Guideline

GL-104229 Zeposia

Formulary

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Zeposia	
Diagnosis	Multiple Sclerosis**
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Claims history is not available (e.g. new to Medicaid) AND the prescriber attests that the patient has taken the requested drug in the previous 120 days

OR

2 - The patient cannot be changed to a preferred* medication due to ONE of the following acceptable reasons:

- Allergy to preferred medications
- Contraindication to or drug interaction with preferred medications
- History of unacceptable/toxic side effects to preferred medications

OR

3 - Patient has had therapeutic failure with a trial of at least 30 days with ONE preferred* medication

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html **This criteria applies to the Central Nervous System (CNS) Agents: Multiple Sclerosis Policy

Product Name: Zeposia	
Diagnosis	Ulcerative Colitis**
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient cannot be changed to a preferred* medication due to ONE of the following acceptable reasons:

- An allergy to preferred medications
- A contraindication to, or drug interaction with, preferred medications
- A history of unacceptable or toxic side effects to preferred medications

OR

2 - Patient has had an inadequate clinical response to a 30 day trial each of TWO preferred* medications

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ohio-health-plans/oh-comm-plan-home/oh-cp-pharmacy.html **This criteria applies to the Gastrointestinal Agents: Ulcerative Colitis Policy

2 . Revision History

Date	Notes
3/1/2022	New

Prior Authorization Guideline

GL-84008 Zokinvy

Formulary

Formulary Note

Guideline Note:

Effective Date:	6/1/2021

1 . Criteria

Product Name: Zokinvy	
Diagnosis	Hutchinson-Gilford Progeria Syndrome
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Hutchinson-Gilford Progeria Syndrome	

Product Name: Zokinvy

Diagnosis	Progeroid Laminopathies
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of processing deficient Progeroid Laminopathies

AND

2 - Documentation of ONE of the following:

- Heterozygous LMNA mutation with progerin-like protein accumulation
- Homozygous or compound heterozygous ZMPSTE24 mutations

Prior Authorization Guideline

GL-96943 Zolinza

Formulary

Formulary Note

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: Zolinza	
Diagnosis	Cutaneous T-Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cutaneous T-cell lymphoma (CTCL)

AND

2 - Patient has progressive, persistent, or recurrent disease on or following two systemic therapies [e.g., Adcetris (brentuximab vedotin), bexarotene, interferon alfa-db, interferon gamma-1b, methotrexate, Poteligeo (mogamulizumab), romidepsin]

Product Name: Zolinza	
Diagnosis	Cutaneous T-Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Zolinza therapy

Product Name: Zolinza	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Zolinza	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Zolinza therapy

Prior Authorization Guideline

GL-108788 Zydelig

Formulary

Formulary Note

Guideline Note:

Effective Date:	8/1/2022

1 . Criteria

Product Name: Zydelig	
Diagnosis	Chronic Lymphocytic Leukemia (CLL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chronic lymphocytic leukemia (CLL)	

AND

2 - ONE of the following:

- Disease has relapsed
- Disease is refractory

Product Name: Zydelig	
Diagnosis	Chronic Lymphocytic Leukemia (CLL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Zydelig therapy

Product Name: Zydelig	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Zydelig	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Zydelig therapy

Prior Authorization Guideline

GL-105186 Zykadia

Formulary

Formulary Note

Guideline Note:

Effective Date:	5/1/2022

1 . Criteria

Product Name: Zykadia	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of non-small cell lung cancer (NSCLC)	

AND

2 - ONE of the following:

- Disease is metastatic
- Disease is recurrent
- Disease is advanced

AND

3 - ONE of the following:

- Tumor is ALK (anaplastic lymphoma kinase)-positive
- Tumor is ROS-1 (gene) positive

Product Name: Zykadia	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of inflammatory myofibroblastic tumor (IMT) with anaplastic lymphoma kinase (ALK) translocation

Product Name: Zykadia	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic brain cancer from non-small cell lung cancer (NSCLC)

AND

2 - ONE of the following:

- Tumor is anaplastic lymphoma kinase (ALK)-positive
- Tumor is ROS1-positive

Product Name: Zykadia	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC), Soft Tissue Sarcoma, Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Zykadia therapy

Product Name: Zykadia	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Zykadia	
Diagnosis	NCCN Recommended Regimens

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Zykadia therapy

2 . Revision History

Date	Notes
3/24/2022	Added clinical criteria for ROS1-positive or ALK-positive brain metast ases from NSCLC

Prior Authorization Guideline

GL-108779 Zytiga

Formulary

Formulary Note

Guideline Note:

Effective Date:	8/1/2022

1 . Criteria

Product Name: Brand Zytiga, generic abiraterone	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of prostate cancer	

AND

2 - ONE of the following:

2.1 Disease is metastatic

OR

2.2 Disease is regional node positive (e.g., N1)

OR

2.3 Patient is in a very-high-risk group receiving external beam radiation therapy (EBRT)

AND

3 - Used in combination with prednisone

AND

4 - ONE of the following:

4.1 Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

OR

4.2 Patient has had bilateral orchiectomy

AND

5 - If the request is for the 500 mg (milligram) tablet, the prescriber provides a reason or special circumstance the patient cannot take abiraterone 250 mg

Product Name: Brand Zytiga, generic abiraterone	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Brand Zytiga, generic abiraterone	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Brand Zytiga, generic abiraterone	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Zytiga therapy

Prior Authorization Guideline

GL-81146 Zyvox

Formulary

Formulary Note

Guideline Note:

Effective Date:	4/1/2021

1 . Criteria

Product Name: Brand Zyvox*, generic linezolid*	
Diagnosis	Labeled Uses
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 For continuation of therapy upon hospital discharge

OR

1.2 As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR

1.3 BOTH of the following:

1.3.1 ONE of the following diagnoses:

- Nosocomial pneumonia
- Community-acquired pneumonia
- Skin and skin structure infections (complicated and uncomplicated)

AND

1.3.2 Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Zyvox

OR

1.4 Invasive infection caused by or likely to be caused by vancomycin-resistant Enterococcus faecium (VRE)

Notes	*Approval Duration: For vancomycin-resistant Enterococcus faecium, authorization will be issued for 28 days. For osteomyelitis, authorization will be issued for the requested duration, not to exceed 6 weeks. All other approvals will be issued for 14 days.

Product Name: Brand Zyvox*, generic linezolid*	
Diagnosis	Off label Uses
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of therapy upon hospital discharge **OR** **2** - As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication **OR** **3** - The drug has been recognized for treatment of the indication by the Infectious Diseases Society of America (IDSA)	
Notes	*Approval Duration: Based on provider and IDSA recommended treat ment durations, not to exceed 6 months.

2 . Revision History

Date	Notes
2/22/2021	Updated osteomyelitis authorization duration to match treatment guid elines