UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2023 P 2273-3 |
| Program | Prior Authorization/Medical Necessity |
| Medication | Cibinqo™ (abrocitinib) tablets |
| P&T Approval Date | 4/2022, 7/2022, 3/2023 |
| Effective Date | 6/1/2023;<br>Oxford only: 6/1/2023 |

**1. Background:**

Cibinqo is a Janus kinase (JAK) inhibitor indicated for the treatment of adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable.

*Limitation of Use:*
Cibinqo is not recommended in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants.

**2. Coverage Criteria[a]:**

**A. Atopic Dermatitis**

1. **Initial Authorization**

a. **Cibinqo** will be approved based on **all** of the following criteria:

(1) Diagnosis of moderate-to-severe chronic atopic dermatitis

**-AND-**

(2) **One** of the following:

(a) **Both** of the following:

i. History of failure, contraindication, or intolerance to **two** of the following therapeutic classes of topical therapies (document drug, date of trial, and/or contraindication to medication)**:**

(a) Medium to very-high potency topical corticosteroid [e.g., Elocon (mometasone furoate), Synalar (fluocinolone acetonide), Lidex (fluocinonide)]
(b) Topical calcineurin inhibitor [e.g., pimecrolimus (generic Elidel), tacrolimus (generic Protopic)].
(c) Eucrisa (crisaborole)[¥]

**-AND-**

ii. **One** of the following:

a. **Both** of the following^:

- Submission of medical records (e.g., chart notes, laboratory values) documenting a 3 month trial [b] of a systemic drug product for the treatment of atopic dermatitis [examples include, but are not limited to, Adbry (tralokinumab-ldrm), Dupixent (dupilumab), etc.[Ω]] (prescription claims history may be used in conjunction as documentation of medication use, dose, and duration)

**-AND-**

- Physician attests that the patient was not adequately controlled with the documented systemic drug product [b]

**-OR-**

b. Physician attests that systemic treatment with **both** of the following, FDA-approved chronic atopic dermatitis therapies is inadvisable. (Document drug and contraindication rationale) ^

- Adbry (tralokinumab-ldrm)
- Dupixent (dupilumab)

**-OR-**

c. Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria[5]).

**-OR-**

(b) **Both** of the following:

i. Patient is currently on Cibinqo therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

**-AND-**

ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Pfizer dermatology patient access program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Cibinqo*

**-AND-**

(3) Patient is **not** receiving Cibinqo in combination with any of the following:

(a) Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm), Dupixent (dupilumab)]
(b) Janus kinase inhibitor [e.g., Rinvoq (upadicitinib), Xeljanz/XR (tofacitinib), Olumiant (baricitinib), Opzelura (topical ruxolitinib)]
(c) Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

**-AND-**

(4) Prescribed by **one** of the following:

(a) Dermatologist
(b) Allergist
(c) Immunologist

***** Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Pfizer dermatology patient access program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

**Authorization will be issued for 12 months.**

2. **Reauthorization**

a. **Cibinqo** will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Cibinqo therapy

**-AND-**

(2) Patient is not receiving Cibinqo in combination with any of the following:

(a) Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm), Dupixent (dupilumab)]
(b) Janus kinase inhibitor [e.g., Rinvoq (upadicitinib), Xeljanz/XR (tofacitinib), Olumiant (baricitinib), Opzelura (topical ruxolitinib)]
(c) Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

**-AND-**

(3) Prescribed by or in consultation with **one** of the following:

(a) Dermatologist
(b) Allergist
(c) Immunologist

**Authorization will be issued for 12 months.**

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.
[b] For Connecticut business, only a 60-day trial will be required. For Kentucky and Mississippi business only a 30-day trial will be required.
^ Tried/failed alternative(s) are supported by FDA labeling.

[¥] Eucrisa requires prior authorization.

Table 1: Relative potencies of topical corticosteroids[3]

| 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 |

Table 2: Systemic immunomodulatory agents recommended by the 2014 American Academy of Dermatology guidelines for the treatment of refractory atopic dermatitis [Ω,4]

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| Cyclosporine |
| Azathioprine |
| Methotrexate |
| Mycophenolate mofetil |

**3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

**4. References:**


1. Cibinqo [package insert]. New York, NY: Pfizer Inc.; February 2023.
2. Eichenfield LF, Tom WL, Chamlin SL et al. Guidelines of care for the management of atopic dermatitis: section 1. Diagnosis and assessment of atopic dermatitis. J Am Acad Dermatol. 2014; 70(1):338-51.
3. Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol. 2014; 71(1):116-32.
4. Sidbury R, Davis DM, Cohen DE, et al. Guidelines of care for the management of atopic dermatitis: Section 3. Management and treatment with phototherapy and systemic agents. J Am Acad Dermatol. 2014 Aug;71(2):327-49.
5. American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Arlington, VA: American Psychiatric Publishing. 2013.


| Program | Prior Authorization/Medical Necessity – Cibinqo (abrocitnib) |
|---|---|
| **Change Control** | |
| 4/2022 | New program |
| 7/2022 | Removed age requirement from initial authorization criteria for atopic dermatitis. Updated state mandate footnote to include Mississippi. |
| 3/2023 | Updated background to reflect expanded indication for patients 12 years of age and older. Updated step requirement to generic Elidel and Protopic and removed footnote. Updated reference. |