UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2023 P 2014-28 |
| Program | Prior Authorization/Medical Necessity - Long-Acting Opioid Pain Medications |
| Medication | **Includes both brand and generic versions of the listed products unless otherwise noted:** fentanyl transdermal patch (generic Duragesic®) 12, 25, 50, 75, 100 mcg/hr, fentanyl transdermal patch 37.5, 62.5, 87.5 mcg/hr^, hydrocodone extended-release capsules (generic Zohydro™ ER), hydrocodone extended-release tablets (generic Hysingla™ ER), hydromorphone extended-release (generic Exalgo®), Hysingla ER^, methadone, morphine sulfate controlled-release capsules (generic Avinza®), morphine sulfate controlled-release tablets (generic MS Contin®), morphine sulfate sustained-release capsules (generic Kadian®), MS Contin^, Nucynta® ER (tapentadol extended-release), oxycodone controlled-release (authorized generic for OxyContin®)^, OxyContin^, oxymorphone extended-release (generic Opana® ER), Xtampza® ER (oxycodone extended-release) |
| P&T Approval Date | 2/2014, 4/2014, 1/2015, 4/2015, 10/2015, 7/2016, 8/2016, 10/2016, 12/2016, 1/2017, 3/2017, 5/2017, 7/2017, 8/2017, 2/2018, 6/2018, 4/2019, 8/2019, 10/2019, 12/2019, 4/2020, 5/2021, 9/2021, 4/2022, 8/2022, 12/2022, 8/2023, 10/2023 |
| Effective Date | 1/1/2024 |

**1. Background:**

Long-acting opioid analgesics, fentanyl transdermal patch, hydromorphone extended-release, hydrocodone extended-release capsules, Hysingla ER, methadone, morphine sulfate controlled-release capsules, morphine sulfate sustained-release capsules, MS Contin, Nucynta ER, OxyContin, oxymorphone extended-release, and Xtampza ER are indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid is needed for an extended period of time and for which alternative treatment options are not appropriate. They are not intended for use as an as needed analgesic.

Long-acting opioids are not indicated for pain in the immediate postoperative period (the first 12-24 hours following surgery), or if the pain is mild, or not expected to persist for an extended period of time. They are only indicated for postoperative use if the patient is already receiving the drug prior to surgery or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time. Physicians should individualize treatment, moving from parenteral to oral analgesics as appropriate.

Long-acting opioids should not be used in treatment naïve patients. Physicians should individualize treatment in every case, initiating therapy at the appropriate point along a

progression from non-opioid analgesics, such as non-steroidal anti-inflammatory drugs and acetaminophen to opioids in a plan of pain management such as those outlined by the World Health Organization, the Agency for Healthcare Research and Quality, the Federation of State Medical Boards Model Guidelines, or the American Pain Society.

The CDC recommends the following best practices in the prescription of long-acting opioids:

- Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain.
- Before starting opioid therapy, treatment goals should be established with patients that include realistic goals for pain and function and should consider how therapy will be discontinued if benefits do not outweigh risks. For some clinical contexts (e.g., headache or fibromyalgia), the expected benefits of initiating opioids are unlikely to outweigh the risks. Track pain and function at every visit (at least every 3 months) using a brief, validated instrument. Continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.
- When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended release/long-acting opioids.
- Document the daily morphine milligram equivalent (MME) in mg/day from all sources of opioids. Access the state prescription drug monitoring program (PDMP) data at treatment initiation and periodically during treatment.
- Caution should be used when opioids are prescribed with benzodiazepines concurrently. Screen for past and current substance abuse and for severe depression, anxiety, and PTSD prior to initiation.
- Benefits and risks of toxicology testing should be considered to assess for prescribed and nonprescribed controlled substances.
- Avoid escalating doses above 50-90 mg/day MME unless sustained meaningful improvement in pain and function is attained.
- Clinicians should evaluate benefits and harms of continued therapy at least every 3 months. If benefits do not outweigh harms, physicians should maximize other therapies and work closely with the patients to gradually reduce or taper opioids. Evaluation should include assessment of substance use disorder/opioid dependence. Validated scales (such as the DAST-10) are available at www.drugabuse.gov.

**Section Overview**

Section 2: Medical Necessity Coverage Criteria for Book of Business
Section 3: Medical Necessity Coverage Criteria for State of Florida, Maryland, West Virginia
Section 4: Medical Necessity Coverage Criteria for State of Louisiana

**2. Coverage Criteria[a] (refer to section overview for state specific criteria and supply limit coverage criteria)**

**A. Cancer or End of Life (defined as a < 2 year life expectancy) related pain[b]**

1. **Fentanyl transdermal patch (generic Duragesic) 12, 25, 50, 75, 100 mcg/hr, methadone, and morphine sulfate controlled-release tablets (generic MS Contin)** will be approved for cancer related pain based on the following criterion:

   a. Patient requires treatment with opioids due to active cancer diagnosis or end of life related pain (document cancer diagnosis or for end of life, expectancy of < 2 years.)

2. **Fentanyl transdermal patch 37.5, 62.5, 87.5 mcg/hr^, hydrocodone extended-release capsules (generic Zohydro ER), hydrocodone extended-release tablets (generic Hysingla ER), hydromorphone extended-release (generic Exalgo), Hysingla ER^, morphine sulfate controlled-release capsules (generic Avinza), morphine sulfate sustained-release capsules (generic Kadian), MS Contin^, Nucynta ER, oxycodone controlled-release (authorized generic for OxyContin)^, OxyContin^, oxymorphone extended release (generic Opana ER), and Xtampza ER [Applies to all brand and generic versions of listed products except generic morphine sulfate controlled-release tablets (generic MS Contin) and fentanyl transdermal patch (generic Duragesic strengths)]** will be approved based on **BOTH** of the following criteria:

   a. Patient requires treatment with opioids due to active cancer diagnosis or end of life related pain (document cancer diagnosis or for end of life, expectancy of < 2 years.)

   -AND-

   b. **ONE** of the following:

      (1) History of failure, contraindication or intolerance to the following (Document date of trial):

         (a) morphine sulfate controlled-release tablets (generic MS Contin)[d]

      -OR-

      (2) Patient is established on pain therapy with the requested medication for cancer-related or end of life pain (< 2 years life expectancy), and the medication is not a new regimen for the treatment of cancer-related or end of life (< 2 years life expectancy) pain.

-OR-

(3) Request is for **hydrocodone extended-release tablets (generic Hysingla ER), Hysingla ER^, oxycodone controlled-release (authorized generic for OxyContin)^, OxyContin^** or **Xtampza ER** and the patient has risk factors for substance abuse

**Authorization will be issued for 24 months up to the dose allowed by supply limit review (please refer supply limit criteria). If the patient is <u>currently</u> taking the requested long-acting opioid OR was recently switched from another long-acting opioid and does not meet the medical necessity initial authorization criteria requirements for long-acting opioids, a denial should be issued and a 90-day authorization may be authorized for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. There is no limit to the number of 90-day authorizations that may be granted.**

**B. Non-cancer and Non-End of Life pain**

1. **Initial Authorization**

a. **Fentanyl transdermal patch (generic Duragesic) 12, 25, 50, 75, 100 mcg/hr, methadone, and morphine sulfate controlled-release tablets (generic MS Contin)** will be approved based on **<u>ALL</u>** of the following criteria:

(1) Prescriber attests to **<u>BOTH</u>** of the following:
- Patient has been screened for substance abuse/opioid dependence
- Pain is moderate to severe and expected to persist for an extended period of time (chronic)

-AND-

(2) Treatment goals are defined and include estimated duration of treatment (must document treatment goals)

-AND-

(3) Patient has been screened for underlying depression and/or anxiety. If applicable, any underlying conditions have been or will be addressed

-AND-

(4) **<u>ONE</u>** of the following:

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

i. The patient is being treated for moderate to severe chronic pain that is **non-neuropathic** (see below for neuropathic pain and fibromyalgia sections)

-AND-

ii. **ONE** of the following:

a) Prior to the start of therapy with the long-acting opioid, the patient has failed an adequate (minimum of 4 week) trial of a short-acting opioid. (Document drug(s) and date of trial).

-OR-

b) The patient is new to the plan (as evidenced by coverage effective date of less than or equal to 120 days) and is currently established on the requested long-acting opioid.

-OR-

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

i. The patient is being treated for moderate to severe **neuropathic pain** (e.g., neuralgia, neuropathy) (See below for fibromyalgia section)

-AND-

ii. **ONE** of the following:

a) **BOTH** of the following:

1) Unless it is contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin titrated to a therapeutic dose.[c] (Document date of trial)

2) Unless it is contraindicated, the patient has not exhibited an adequate response to at least 6 weeks of treatment with a tricyclic antidepressant titrated to the maximum tolerated dose.[c] (Document drug, and date of trial)

-OR-

b) The patient is new to the plan (as evidenced by coverage effective date of less than or equal to 120 days) and is currently established on the requested long-acting opioid.

-OR-

(c) **ALL** of the following:

i. The patient is being treated for moderate to severe **fibromyalgia**

-AND-

ii. Submission of medical records (e.g., chart notes) documenting the patient is currently established on a long-acting opioid

-AND-

iii. Submission of medical records (e.g., chart notes) documenting the patient has experienced a benefit from opioid therapy

b. **Fentanyl transdermal patch 37.5, 62.5, 87.5 mcg/hr^, hydrocodone extended-release capsules (generic Zohydro ER), hydrocodone extended-release tablets (generic Hysingla ER), hydromorphone extended-release (generic Exalgo), Hysingla ER^, morphine sulfate controlled-release capsules (generic Avinza), morphine sulfate sustained-release capsules (generic Kadian), MS Contin^, Nucynta ER, oxycodone controlled-release (authorized generic for OxyContin)^, OxyContin^, oxymorphone extended-release (generic Opana ER), and Xtampza ER [Applies to all brand and generic versions of listed products except generic morphine sulfate controlled-release tablets (generic MS Contin) and fentanyl transdermal patch (generic Duragesic strengths)]** will be approved for non-cancer and non-end of life related pain based on **ALL** of the following criteria:

(1) The prescriber attests to **BOTH** of the following:

- Patient has been screened for substance abuse/opioid dependence
- Pain is moderate to severe and expected to persist for an extended period of time (chronic)

-AND-

(2) Treatment goals are defined and include estimated duration of treatment (must document treatment goals)

-AND-

(3) Patient has been screened for underlying depression and/or anxiety. If applicable, any underlying conditions have been or will be addressed

-AND-

(4) **ONE** of the following:

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

i. The patient is being treated for moderate to severe chronic pain that is **non-neuropathic** (see below for neuropathic pain and fibromyalgia sections)

-AND-

ii. **ONE** of the following:

a) Prior to the start of therapy with the long-acting opioid, the patient has failed an adequate (minimum of 4 week) trial of a short-acting opioid. (Document drug(s) and date of trial).

-OR-

b) The patient is new to the plan (as evidenced by coverage effective date of less than or equal to 120 days) and is currently established on the requested long-acting opioid.

-OR-

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

i. The patient is being treated for moderate to severe **neuropathic pain** (e.g., neuralgia, neuropathy) (See below for fibromyalgia section)

-AND-

ii. **ONE** of the following:

a) **BOTH** of the following:

1) Unless it is contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin titrated to a therapeutic dose.[c] (Document date of trial)

2) Unless it is contraindicated, the patient has not exhibited an adequate response to at least 6 weeks of treatment with a tricyclic antidepressant titrated to the maximum tolerated dose.[c] (Document drug, and date of trial)

-OR-

b) The patient is new to the plan (as evidenced by coverage effective date of less than or equal to 120 days) and is currently established on the requested long-acting opioid.

-OR-

(c) **ALL** of the following:

i. The patient is being treated for moderate to severe **fibromyalgia**

-AND-

ii. Submission of medical records (e.g., chart notes) documenting the patient is currently established on a long-acting opioid

-AND-

iii. Submission of medical records (e.g., chart notes) documenting the patient has experienced a benefit from opioid therapy

-AND-

(5) One of the following:

(a) The patient has a history of failure, contraindication or intolerance to the following (Document date of trial):

i) morphine sulfate controlled-release tablets (generic MS Contin)[d]

-OR-

(b) Request is for **hydrocodone ER tablets (generic Hysingla ER), Hysingla ER^, oxycodone controlled-release (authorized generic for OxyContin)^, OxyContin^** or **Xtampza ER** and the patient has risk factors for substance abuse

**Authorization will be issued for 6 months for non-cancer and non-end of life pain up to the dose allowed by supply limit review (please refer to supply limit criteria). If the member is <u>currently</u> taking the requested long-acting opioid OR was recently switched from another long-acting opioid and does not meet the medical necessity initial authorization criteria requirements for long-acting opioids, a denial should be issued and a90-day authorization may be authorized for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. There is no limit to the number of 90-day authorizations that may be granted.**

2. **Reauthorization**

a. **Fentanyl transdermal patch, hydrocodone extended-release capsules (generic Zohydro ER), hydrocodone extended-release tablets (generic Hysingla ER), hydromorphone extended-release (generic Exalgo), Hysingla ER^, methadone, morphine sulfate controlled-release capsules (generic Avinza), morphine sulfate controlled-release tablets (generic MS Contin), morphine sulfate sustained-release capsules (generic Kadian), MS Contin^, Nucynta ER, oxycodone controlled-release (authorized generic for OxyContin)^, OxyContin^, oxymorphone extended-release (generic Opana ER), and Xtampza ER** [Applies to all brand and generic versions of listed products)] will be reauthorized based on **all** of the following criteria:

(1) Documented meaningful improvement in pain and function when assessed against treatment goals (Document improvement in function or pain score improvement)

-AND-

(2) Document rationale for not tapering or discontinuing opioid if treatment goals are not being met

-AND-

(3) Prescriber attests to **<u>BOTH</u>** of the following:

- Patient has been screened for substance abuse/opioid dependence

- Pain is moderate to severe and expected to persist for an extended period of time (chronic)

**Authorization will be issued for 6 months for non-cancer and non-end of life pain up to the dose allowed by supply limit review (please refer to supply limit criteria). If the patient is currently taking the requested long-acting opioid OR was recently switched from another long-acting opioid and does not meet the medical necessity reauthorization criteria requirements for long-acting opioids, a denial should be issued and a90-day authorization may be authorized for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. There is no limit to the number of 90-day authorizations that may be granted.**

[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.] Coverage of medications to treat conditions associated with cancer may be approved based on state mandates.
[c.] For Connecticut business, only a 60 day trial will be required. For Kentucky and Mississippi business, only a 30 day trial will be required.
[d.] For Nucynta ER, step therapy not applicable to Colorado business.

**3. Coverage Criteria for the State of Florida, Maryland, West Virginia[a]:**

**A. Cancer or End of Life (defined as a < 2 year life expectancy) related pain[b]**

1. **Fentanyl transdermal patch (generic Duragesic)** 12, 25, 50, 75, 100 mcg/hr**, hydrocodone ER tablets (generic Hysingla ER), Hysingla ER^, methadone, morphine sulfate controlled-release tablets (generic MS Contin), oxycodone controlled-release (authorized generic for OxyContin)^, OxyContin^ and Xtampza ER** will be approved for cancer related pain based on the following criterion:

   a. Patient requires treatment with opioids due to active cancer diagnosis or end of life related pain (document cancer diagnosis or for end of life, expectancy of < 2 years.)

2. **Fentanyl transdermal patch 37.5, 62.5, 87.5 mcg/hr^, hydrocodone extended-release capsules (generic Zohydro ER), hydromorphone extended-release (generic Exalgo), morphine sulfate controlled-release capsules (generic Avinza), morphine sulfate sustained-release capsules (generic Kadian), MS Contin^, Nucynta ER, and oxymorphone extended-release (generic Opana ER) [Applies to all brand and generic versions of listed products except generic morphine sulfate controlled-release tablets (generic MS Contin) and fentanyl transdermal patch**

**(generic Duragesic strengths)]** will be approved for non-cancer and non-end of life related pain based on **BOTH** of the following criteria:

a. Patient requires treatment with opioids due to active cancer diagnosis or end of life related pain (document cancer diagnosis or for end of life, expectancy of < 2 years.)

-AND-

b. **ONE** of the following:

(1) History of failure, contraindication or intolerance to the following: (Document date of trial)

(a) morphine sulfate controlled-release tablets (generic MS Contin)

-OR-

(2) Patient is established on pain therapy with the requested medication for cancer-related or end of life pain (< 2 years life expectancy), and the medication is not a new regimen for the treatment of cancer-related or end of life (< 2 years life expectancy) pain.

**Authorization will be issued for 24 months up to the dose allowed by supply limit review (please refer to supply limit criteria). If the patient is currently taking the requested long-acting opioid OR was recently switched from another long-acting opioid and does not meet the medical necessity initial authorization criteria requirements for long-acting opioids, a denial should be issued and a 90-day authorization may be authorized for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. There is no limit to the number of 90-day authorizations that may be granted.**

**B. Non-cancer and Non-End of Life pain**

1. **Initial Authorization**

a. **Fentanyl transdermal patch (generic Duragesic)** 12, 25, 50, 75, 100 mcg/hr**, hydrocodone ER tablets (generic Hysingla ER), Hysingla ER^, methadone, morphine sulfate controlled-release tablets (generic MS Contin), oxycodone controlled-release (authorized generic for OxyContin)^, OxyContin^ and Xtampza ER** will be approved based on the following criteria:

(1) Prescriber attests to **BOTH** of the following:

- Patient has been screened for substance abuse/opioid dependence

- Pain is moderate to severe and expected to persist for an extended period of time (chronic)

-AND-

(2) Treatment goals are defined and include estimated duration of treatment (must document treatment goals).

-AND-

(3) Patient has been screened for underlying depression and/or anxiety. If applicable, any underlying conditions have been or will be addressed.

-AND-

(4) **ONE** of the following:

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

i. The patient is being treated for moderate to severe chronic pain that is **non-neuropathic** (see below for neuropathic pain and fibromyalgia sections)

-AND-

ii. **ONE** of the following:

a) Prior to the start of therapy with the long-acting opioid, the patient has failed an adequate (minimum of 4 week) trial of a short-acting opioid. (Document drug(s) and date of trial).

-OR-

b) The patient is new to the plan (as evidenced by coverage effective date of less than or equal to 120 days) and is currently established on the requested long-acting opioid.

-OR-

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

i. The patient is being treated for moderate to severe **neuropathic pain** (e.g., neuralgia, neuropathy) (See below for fibromyalgia section)

-AND-

ii. **ONE** of the following:

a) **BOTH** of the following:

1) Unless it is contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin titrated to a therapeutic dose. (Document date of trial)

2) Unless it is contraindicated, the patient has not exhibited an adequate response to at least 6 weeks of treatment with a tricyclic antidepressant titrated to the maximum tolerated dose. (Document drug, and date of trial)

-OR-

b) The patient is new to the plan (as evidenced by coverage effective date of less than or equal to 120 days) and is currently established on the requested long-acting opioid.

-OR-

(c) **ALL** of the following:

i. The patient is being treated for moderate to severe **fibromyalgia**

-AND-

ii. Submission of medical records (e.g., chart notes) documenting the patient is currently established on a long-acting opioid

-AND-

iii. Submission of medical records (e.g., chart notes) documenting the patient has experienced a benefit from opioid therapy

b. **Fentanyl transdermal patch** 37.5, 62.5, 87.5 mcg/hr^**, hydrocodone extended-release capsules (generic Zohydro), hydromorphone extended-release (generic Exalgo), morphine sulfate controlled-release capsules (generic Avinza), morphine sulfate sustained-release capsules (generic Kadian) MS Contin^, Nucynta ER, and oxymorphone extended-release (generic Opana ER) [Applies to all**

**brand and generic versions of listed products except generic morphine sulfate controlled-release tablets (generic MS Contin) and fentanyl transdermal patch (generic Duragesic strengths)]** will be approved for non-cancer and non-end of life related pain based on the following criteria:

(1) Prescriber attests to **BOTH** of the following:
- Patient has been screened for substance abuse/opioid dependence
- Pain is moderate to severe and expected to persist for an extended period of time (chronic)

-AND-

(2) Treatment goals are defined and include estimated duration of treatment (must document treatment goals)

-AND-

(3) Patient has been screened for underlying depression and/or anxiety. If applicable, any underlying conditions have been or will be addressed

-AND-

(4) **ONE** of the following:

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

i. The patient is being treated for moderate to severe chronic pain that is **non-neuropathic** (see below for neuropathic pain and fibromyalgia sections)

-AND-

ii. **ONE** of the following:

a) Prior to the start of therapy with the long-acting opioid, the patient has failed an adequate (minimum of 4 week) trial of a short-acting opioid. (Document drug(s) and date of trial).

-OR-

b) The patient is new to the plan (as evidenced by coverage effective date of less than or equal to 120 days) and is currently established on the requested long-acting opioid.

-OR-

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

i. The patient is being treated for moderate to severe **neuropathic pain** (e.g., neuralgia, neuropathy) (See below for fibromyalgia section)

-AND-

ii. **ONE** of the following:

a) **BOTH** of the following:

1) Unless it is contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin titrated to a therapeutic dose. (Document date of trial)

2) Unless it is contraindicated, the patient has not exhibited an adequate response to at least 6 weeks of treatment with a tricyclic antidepressant titrated to the maximum tolerated dose. (Document drug, and date of trial)

-OR-

b) The patient is new to the plan (as evidenced by coverage effective date of less than or equal to 120 days) and is currently established on the requested long-acting opioid.

-OR-

(c) **ALL** of the following:

i. The patient is being treated for moderate to severe **fibromyalgia**

-AND-

ii. Submission of medical records (e.g., chart notes) documenting the patient is currently established on a long-acting opioid

-AND-

iii. Submission of medical records (e.g., chart notes) documenting the patient has experienced a benefit from opioid therapy

-AND-

(5) The patient has a history of failure, contraindication or intolerance to the following (Document date of trial):

(a) morphine sulfate controlled-release tablets (generic MS Contin)

**Authorization will be issued for 6 months for non-cancer and non-end of life pain up to the dose allowed by supply limit review (please refer to supply limit criteria). If the patient is currently taking the requested long-acting opioid OR was recently switched from another long-acting opioid and does not meet the medical necessity initial authorization criteria requirements for long-acting opioids, a denial should be issued and a 90-day authorization may be authorized for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. There is no limit to the number of 90-day authorizations that may be granted.**

2. **Reauthorization**

a. **Fentanyl transdermal patch, hydrocodone extended-release capsules (generic Zohydro ER), hydrocodone extended-release tablets (generic Hysingla ER), hydromorphone extended-release (generic Exalgo), Hysingla ER^, methadone, morphine sulfate controlled-release capsules (generic Avinza), morphine sulfate controlled-release tablets (generic MS Contin), morphine sulfate sustained-release capsules (generic Kadian), MS Contin^, Nucynta ER, oxycodone controlled-release^ (authorized generic for OxyContin), OxyContin^, oxymorphone extended-release (generic Opana ER), and Xtampza ER [Applies to all brand and generic versions of listed products]** will be reauthorized based on **ALL** of the following criteria:

(1) Documented meaningful improvement in pain and function when assessed against treatment goals (Document improvement in function or pain score improvement)

-AND-

(2) Document rationale for not tapering or discontinuing opioid if treatment goals are not being met

-AND-

(3) Prescriber attests to **BOTH** of the following:

- Patient has been screened for substance abuse/opioid dependence
- Pain is moderate to severe and expected to persist for an extended period of time (chronic)

**Authorization will be issued for 6 months for non-cancer and non-end of life pain up to the dose allowed by supply limit review (please refer to supply limit criteria). If the patient is currently taking the requested long-acting opioid OR was recently switched from another long-acting opioid and does not meet the medical necessity reauthorization criteria requirements for long-acting opioids, a denial should be issued and a 90-day authorization may be authorized for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. There is no limit to the number of 90-day authorizations that may be granted.**

[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.] Coverage of medications to treat conditions associated with cancer may be approved based on state mandates.

**4. Coverage Criteria for the State of Louisiana[a]:**

**A. Cancer or End of Life (defined as a < 2 year life expectancy) related pain[b]**

1. **Fentanyl transdermal patch (generic Duragesic) 12, 25, 50, 75, 100 mcg/hr, methadone, morphine sulfate controlled-release capsules (generic Avinza), morphine sulfate sustained-release capsules (generic Kadian), and morphine sulfate controlled-release tablets (generic MS Contin)** will be approved for cancer related pain based on the following criterion:

   a. Patient requires treatment with opioids due to active cancer diagnosis or end of life related pain (document cancer diagnosis or for end of life, expectancy of < 2 years.)

2. **Fentanyl transdermal patch 37.5, 62.5, 87.5 mcg/hr^, hydrocodone extended-release capsules (generic Zohydro ER), MS Contin^, Nucynta ER, oxycodone controlled-release (authorized generic for OxyContin)^, OxyContin^, oxymorphone extended-release (generic Opana ER), and Xtampza ER [Applies to all brand and generic versions of listed products except generic morphine sulfate controlled-release tablets (generic MS Contin) and fentanyl transdermal patch (generic Duragesic strengths)]** will be approved based on **BOTH** of the following criteria:

   a. Patient requires treatment with opioids due to active cancer diagnosis or end of life related pain (document cancer diagnosis or for end of life, expectancy of < 2 years.)

   -AND-

   b. **ONE** of the following:

      (1) History of failure, contraindication or intolerance to the following (Document date of trial):

         (a) morphine sulfate controlled-release tablets (generic MS Contin)

      -OR-

      (2) Patient is established on pain therapy with the requested medication for cancer-related or end of life pain (< 2 years life expectancy), and the medication is not a new regimen for the treatment of cancer-related or end of life (< 2 years life expectancy) pain.

      -OR-

      (3) Request is for **oxycodone controlled-release (authorized generic for OxyContin)^, OxyContin^** or **Xtampza ER** and the patient has risk factors for substance abuse

3. **Hydrocodone extended-release tablets (generic Hysingla ER), hydromorphone extended-release (generic Exalgo), Hysingla ER^** will be approved based on **BOTH** of the following criteria:

   a. Patient requires treatment with opioids due to active cancer diagnosis or end of life related pain (document cancer diagnosis or for end of life, expectancy of < 2 years.)

   -AND-

b. **ONE** of the following:

(1) History of failure, contraindication, or intolerance to ONE of the following (Document date of trial):

(a) morphine sulfate controlled-release capsules (generic Avinza)
(b) morphine sulfate sustained-release capsules (generic Kadian)

-OR-

(2) Patient is established on pain therapy with the requested medication for cancer-related or end of life pain (< 2 years life expectancy), and the medication is not a new regimen for the treatment of cancer-related or end of life (< 2 years life expectancy) pain.

-OR-

(3) The patient has risk factors for substance abuse

**Authorization will be issued for 24 months up to the dose allowed by supply limit review (please refer supply limit criteria). If the patient is currently taking the requested long-acting opioid OR was recently switched from another long-acting opioid and does not meet the medical necessity initial authorization criteria requirements for long-acting opioids, a denial should be issued and a90-day authorization may be authorized for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. There is no limit to the number of 90-day authorizations that may be granted.**

**B. Non-cancer and Non-End of Life pain**

1. **Initial Authorization**

a. **Fentanyl transdermal patch (generic Duragesic) 12, 25, 50, 75, 100 mcg/hr, methadone, morphine sulfate controlled-release capsules (generic Avinza), morphine sulfate sustained-release capsules (generic Kadian), and morphine sulfate controlled-release tablets (generic MS Contin)** will be approved based on **ALL** of the following criteria:

(1) Prescriber attests to **BOTH** of the following:
- Patient has been screened for substance abuse/opioid dependence
- Pain is moderate to severe and expected to persist for an extended period of time (chronic)

-AND-

(2) Treatment goals are defined and include estimated duration of treatment (must document treatment goals)

-AND-

(3) Patient has been screened for underlying depression and/or anxiety. If applicable, any underlying conditions have been or will be addressed

-AND-

(4) **ONE** of the following:

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

i. The patient is being treated for moderate to severe chronic pain that is **non-neuropathic** (see below for neuropathic pain and fibromyalgia sections)

-AND-

ii. **ONE** of the following:

a) Prior to the start of therapy with the long-acting opioid, the patient has failed an adequate (minimum of 4 week) trial of a short-acting opioid. (Document drug(s) and date of trial).

-OR-

b) The patient is new to the plan (as evidenced by coverage effective date of less than or equal to 120 days) and is currently established on the requested long-acting opioid.

-OR-

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

i. The patient is being treated for moderate to severe **neuropathic pain** (e.g., neuralgia, neuropathy) (See below for fibromyalgia section)

-AND-

ii. **ONE** of the following:

a) **BOTH** of the following:

1) Unless it is contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin titrated to a therapeutic dose. (Document date of trial)

2) Unless it is contraindicated, the patient has not exhibited an adequate response to at least 6 weeks of treatment with a tricyclic antidepressant titrated to the maximum tolerated dose. (Document drug, and date of trial)

-OR-

b) The patient is new to the plan (as evidenced by coverage effective date of less than or equal to 120 days) and is currently established on the requested long-acting opioid.

-OR-

(c) **ALL** of the following:

i. The patient is being treated for moderate to severe **fibromyalgia**

-AND-

ii. Submission of medical records (e.g., chart notes) documenting the patient is currently established on a long-acting opioid

-AND-

iii. Submission of medical records (e.g., chart notes) documenting the patient has experienced a benefit from opioid therapy

b. **Fentanyl transdermal patch 37.5, 62.5, 87.5 mcg/hr^, hydrocodone extended-release capsules (generic Zohydro ER), MS Contin^, Nucynta ER, oxycodone controlled-release (authorized generic for OxyContin)^, OxyContin^, oxymorphone extended-release (generic Opana ER), and Xtampza ER[Applies to all brand and generic versions of listed products except generic morphine sulfate controlled-release tablets (generic MS Contin) and fentanyl transdermal patch (generic Duragesic strengths)]** will be approved for

non-cancer and non-end of life related pain based on **ALL** of the following criteria:

(1) The prescriber attests to **BOTH** of the following:
- Patient has been screened for substance abuse/opioid dependence
- Pain is moderate to severe and expected to persist for an extended period of time (chronic)

-AND-

(2) Treatment goals are defined and include estimated duration of treatment (must document treatment goals)

-AND-

(3) Patient has been screened for underlying depression and/or anxiety. If applicable, any underlying conditions have been or will be addressed

-AND-

(4) **ONE** of the following:

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

i. The patient is being treated for moderate to severe chronic pain that is **non-neuropathic** (see below for neuropathic pain and fibromyalgia sections)

-AND-

ii. **ONE** of the following:

a) Prior to the start of therapy with the long-acting opioid, the patient has failed an adequate (minimum of 4 week) trial of a short-acting opioid. (Document drug(s) and date of trial).

-OR-

b) The patient is new to the plan (as evidenced by coverage effective date of less than or equal to 120 days) and is currently established on the requested long-acting opioid.

-OR-

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

i. The patient is being treated for moderate to severe **neuropathic pain** (e.g., neuralgia, neuropathy) (See below for fibromyalgia section)

-AND-

ii. **ONE** of the following:

a) **BOTH** of the following:

1) Unless it is contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin titrated to a therapeutic dose. (Document date of trial)

2) Unless it is contraindicated, the patient has not exhibited an adequate response to at least 6 weeks of treatment with a tricyclic antidepressant titrated to the maximum tolerated dose. (Document drug, and date of trial)

-OR-

b) The patient is new to the plan (as evidenced by coverage effective date of less than or equal to 120 days) and is currently established on the requested long-acting opioid.

-OR-

(c) **ALL** of the following:

i. The patient is being treated for moderate to severe **fibromyalgia**

-AND-

ii. Submission of medical records (e.g., chart notes) documenting the patient is currently established on a long-acting opioid

-AND-

iii. Submission of medical records (e.g., chart notes) documenting the patient has experienced a benefit from opioid therapy

-AND-

(5) One of the following:

(a) The patient has a history of failure, contraindication or intolerance to the following (Document date of trial):

i) morphine sulfate controlled-release tablets (generic MS Contin)

-OR-

(b) Request is for **oxycodone controlled-release (authorized generic for OxyContin)^, OxyContin^** or **Xtampza ER** and the patient has risk factors for substance abuse

c. **Hydrocodone extended-release tablets (generic Hysingla ER), hydromorphone extended-release (generic Exalgo), Hysingla ER^**will be approved for non-cancer and non-end of life related pain based on **ALL** of the following criteria:

(1) The prescriber attests to **BOTH** of the following:
- Patient has been screened for substance abuse/opioid dependence
- Pain is moderate to severe and expected to persist for an extended period of time (chronic)

-AND-

(2) Treatment goals are defined and include estimated duration of treatment (must document treatment goals)

-AND-

(3) Patient has been screened for underlying depression and/or anxiety. If applicable, any underlying conditions have been or will be addressed

-AND-

(4) **ONE** of the following:

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

i. The patient is being treated for moderate to severe chronic pain that is **non-neuropathic** (see below for neuropathic pain and fibromyalgia sections)

-AND-

ii. **ONE** of the following:

a) Prior to the start of therapy with the long-acting opioid, the patient has failed an adequate (minimum of 4 week) trial of a short-acting opioid. (Document drug(s) and date of trial).

-OR-

b) The patient is new to the plan (as evidenced by coverage effective date of less than or equal to 120 days) and is currently established on the requested long-acting opioid.

-OR-

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

i. The patient is being treated for moderate to severe **neuropathic pain** (e.g., neuralgia, neuropathy) (See below for fibromyalgia section)

-AND-

ii. **ONE** of the following:

a) **BOTH** of the following:

1) Unless it is contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin titrated to a therapeutic dose. (Document date of trial)

2) Unless it is contraindicated, the patient has not exhibited an adequate response to at least 6 weeks of treatment with a tricyclic antidepressant titrated to the maximum tolerated dose. (Document drug, and date of trial)

-OR-

b) The patient is new to the plan (as evidenced by coverage effective date of less than or equal to 120 days) and is currently established on the requested long-acting opioid.

-OR-

(c) **ALL** of the following:

i. The patient is being treated for moderate to severe **fibromyalgia**

-AND-

ii. Submission of medical records (e.g., chart notes) documenting the patient is currently established on a long-acting opioid

-AND-

iii. Submission of medical records (e.g., chart notes) documenting the patient has experienced a benefit from opioid therapy

-AND-

(5) One of the following:

(a) History of failure, contraindication, or intolerance to ONE of the following (Document date of trial):

i) morphine sulfate controlled-release capsules (generic Avinza)
ii) morphine sulfate sustained-release capsules (generic Kadian)

-OR-

(b) The patient has risk factors for substance abuse

**Authorization will be issued for 6 months for non-cancer and non-end of life pain up to the dose allowed by supply limit review (please refer to supply limit criteria). If the member is currently taking the requested long-acting opioid OR was recently switched from another long-acting opioid and does not meet the medical necessity initial authorization criteria requirements for long-acting opioids, a denial should be issued and a90-day authorization may be authorized for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. There is no limit to the number of 90-day authorizations that may be granted.**

2. **Reauthorization**

a. **Fentanyl transdermal patch, hydrocodone extended-release capsules (generic Zohydro ER), hydrocodone extended-release tablets (generic Hysingla ER), hydromorphone extended-release (generic Exalgo), Hysingla ER^, methadone, morphine sulfate controlled-release capsules (generic Avinza), morphine sulfate**

**controlled-release tablets (generic MS Contin), morphine sulfate sustained-release capsules (generic Kadian), MS Contin^, Nucynta ER, oxycodone controlled-release^ (authorized generic for OxyContin), OxyContin^, oxymorphone extended-release (generic Opana ER), and Xtampza ER** [Applies to all brand and generic versions of listed products)] will be reauthorized based on **all** of the following criteria:

(1) Documented meaningful improvement in pain and function when assessed against treatment goals (Document improvement in function or pain score improvement)

-AND-

(2) Document rationale for not tapering or discontinuing opioid if treatment goals are not being met

-AND-

(3) Prescriber attests to **BOTH** of the following:

- Patient has been screened for substance abuse/opioid dependence
- Pain is moderate to severe and expected to persist for an extended period of time (chronic)

**Authorization will be issued for 6 months for non-cancer and non-end of life pain up to the dose allowed by supply limit review (please refer to supply limit criteria). If the patient is currently taking the requested long-acting opioid OR was recently switched from another long-acting opioid and does not meet the medical necessity reauthorization criteria requirements for long-acting opioids, a denial should be issued and a 90-day authorization may be authorized for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. There is no limit to the number of 90-day authorizations that may be granted.**

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. Coverage of medications to treat conditions associated with cancer may be approved based on state mandates.

**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.
- MMELIMIT (Cumulative Opioid Review) is in place and can be utilized for individual supply limit reviews.

^ Hysingla ER (brand only), fentanyl 37.5, 62.5 and 87.5 mcg/hr, MS Contin (brand only), oxycodone controlled-release (authorized generic for OxyContin), and OxyContin are typically excluded from coverage. Tried/Failed criteria may be in place. Please refer to plan specifics to determine exclusion status.

**4. References:**


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6. OxyContin [package insert]. Stanford, CT: Purdue Pharma; October 2021.
7. Zohydro ER [package insert]. Princeton, NJ: Pernix Therapeutics; March 2021.
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13. Franklin, GM. Opioids for chronic noncancer pain. A position paper of the American Academy of Neurology. Neurology. 2014;83:1277-1284.
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| Program | Prior Authorization/Medical Necessity - Long-Acting Opioid Pain Medications |
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| **Change Control** | |
| Date | Change |
| 2/2014 | New program |
| 4/2014 | Removed step criteria |
| 1/2015 | Added additional products: Hysingla, MS Contin, hydromorphone and Oramorph. Added step criteria for cancer and non-cancer chronic pain with differentiation between neuropathic and non-neuropathic pain. Updated references to include new products' prescribing information, the AAN position paper, and neuropathic pain treatment guidelines. |
| 4/2015 | Added Embeda and removed Oramorph from current criteria. Added exemption language for Connecticut. |
| 10/2015 | Provided clarification regarding which brand and generic versions of listed products are included in the criteria (e.g. which generic morphine sulfate product is preferred and which are non-preferred). Added criteria for patients under the age of 18 years. Added state specific criteria for Maryland and Maine. |
| 7/2016 | Added Xtampza ER as preferred product. Added Indiana and West Virginia step therapy mandate. |
| 8/2016 | Added requirement for the submission of the Long-Acting Opioid Prior Authorization Fax Form. Revised criteria to include recommendation from the CDC Guidelines to require trial of a short-acting opioid prior to LAO initiation. Added requirement for medical record documentation of cancer diagnosis. Added requirement for documentation of MED and specific medication trial information. Added generic MS Contin and fentanyl transdermal to state specific criteria where applicable. Added provider attestation language. Removed specific criteria for the state of Maine. Added state specific criteria for Florida, West Virginia and Connecticut. Added supply limit criteria to Medical Necessity Review. Updated references. |
| 10/2016 | Added AR state mandate to supply limit review section. Removed requirement for the Long-Acting Opioid Prior Authorization Fax Form. Revised reauthorization to include the |

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| | request for all information collected from open-ended questions in lieu of Long-Acting Opioid Prior Authorization Fax Form. |
| 12/2016 | Changed taper allowance from a one-time authorization to a 60-day authorization. Added end of life diagnoses to cancer pain section. Updated supply limits section to allow pre-approval of higher strengths where applicable for dose consolidation. Removed ceiling limit for cancer and end of life diagnoses. Added CT footnote for the trial and failure of short-acting opioids for the book of business criteria. |
| 1/2017 | Added requirement for trial and failure of Xtampza ER prior to approval for OxyContin and oxycodone controlled-release for initial authorization and reauthorization criteria. Clarified that maximum 60-day fill should only be authorized one time. |
| 3/2017 | Added criteria for members new to the plan that should be reviewed as continuation of therapy for preferred products. |
| 5/2017 | Removed Opana ER as a preferred step one product. Added new product Arymo ER to criteria. |
| 7/2017 | Removed fentanyl transdermal as a preferred step one product. Updated reauthorization criteria to review instruments used to assess patients rather than specific scores. Removed requirement for provider attestation for cancer and end of life pain diagnoses. Added Morphabond ER, Troxyca ER, and Vantrela ER. |
| 8/2017 | Updated fentanyl supply limits. |
| 2/2018 | Added morphine sulfate ER (generic MS Contin), Duragesic, and methadone to the program. Added criteria for State of Connecticut. Revised provider attestation and added to initial authorization. Revised reauthorization criteria. |
| 6/2018 | Removed supply limit criteria. Will now utilize MEDLIMIT criteria. Removed Vantrela ER and Troxyca ER- products never brought to market. |
| 4/2019 | Revised MED to MME. Added fentanyl step for brand Duragesic requests. Removed medical record submission requirement for cancer related pain. |
| 8/2019 | Added continuation of therapy requirement for FL |
| 10/2019 | Added a note for stage four advanced metastatic cancer and state mandates. |
| 12/2019 | Removed Embeda from criteria. Added Arymo ER as first step drug for Maryland and West Virginia. |
| 5/2021 | Removed products no longer on the market. Revised provider attestation. Added requirements for documentation of treatment goals and screening for underlying depression and anxiety. Administrative changes and references updated. |
| 9/2021 | Added methadone to reauthorizations. Added hydromorphone to authorizations. Added documentation of treatment goals and |

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| | screening for underlying depression and anxiety to Maryland non-cancer/EOL initial authorization. Revised duration of trial for Connecticut mandates. |
| 4/2022 | Added cancer medications state mandate note. |
| 8/2022 | Moved Nucynta ER and Xtampza to require step through morphine sulfate extended-release (generic MS Contin). Removed fentanyl (generic Duragesic) as a step one option. Updated state mandate sections. |
| 12/2022 | Updated coverage criteria for fibromyalgia to only allow for continuation of therapy for patients already established on therapy and for patients who have experienced a benefit. |
| 8/2023 | Updated background information with updated CDC guidelines. Updated authorizations to allow for unlimited 90 day approvals for transition if criteria is not met. |
| 10/2023 | Removed “routine audit” language from criteria. |