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UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 2014-23
Program	Prior Authorization/Medical Necessity - Long-Acting Opioid Pain Medications
Medication	**Includes both brand and generic versions of the listed products unless otherwise noted:** morphine sulfate controlled-release capsules (generic Avinza), methadone, Duragesic (fentanyl transdermal)^ 12, 25, 50, 75, 100 mcg/hr^, hydromorphone extended-release (generic Exalgo), fentanyl transdermal (37.5, 62.5, 87.5 mcg/hr), Hysingla ER^ (hydrocodone extended-release^), morphine sulfate sustained-release capsules^ (generic Kadian), morphine sulfate controlled-release (generic MS Contin), MS Contin, Nucynta ER (tapentadol extended-release), (oxymorphone extended-release), OxyContin^ (oxycodone controlled-release^, includes authorized generic), Xtampza ER (oxycodone extended-release), Zohydro ER^ (hydrocodone 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
Effective Date	12/1/2021; Oxford only: 12/1/2021

1. Background:

Long-acting opioid analgesics, morphine sulfate controlled-release capsules, Duragesic (including fentanyl transdermal), hydromorphone ER, Hysingla ER, morphine sulfate sustained-release capsules, MS Contin, Nucynta ER, oxycodone hcl ER, OxyContin, oxymorphone ER, Xtampza ER and Zohydro 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

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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 and the American Academy of Neurology 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. 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. Currently all states except for Missouri have a PDMP.
- To avoid increased risk of respiratory depression, long-acting opioids should not be prescribed concurrently with benzodiazepines. Screen for past and current substance abuse and for severe depression, anxiety, and PTSD prior to initiation.
- Use random urine drug screening prior to initiation and periodically during treatment with a frequency according to risk.
- Use a patient treatment agreement, signed by both the patient and prescriber that address risks of use and responsibilities of the patient. Avoid escalating doses above 50-90 mg/day MME unless sustained meaningful improvement in pain and function is attained, and not without consultation with a pain management specialist.
- Clinicians should evaluate benefits and harms of continued therapy at least every 3 months. If benefits do not outweigh harms, opioids should be tapered and discontinued. 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
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Section 6: Medical Necessity Coverage Criteria for State of West Virginia

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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**, Nucynta ER, methadone, morphine sulfate controlled-release tablets (generic MS Contin), 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. **Morphine sulfate controlled-release capsules (generic Avinza), Duragesic^, fentanyl transdermal patch** (37.5, 62.5, 87.5 mcg/hr) **^, Hysingla ER^, hydromorphone extended release (generic Exalgo) morphine sulfate sustained-release capsules (generic Kadian), MS Contin, Oxycontin^, oxycodone controlled-release (authorized generic for OxyContin)^, oxymorphone extended release and Zohydro 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 a trial of **ALL** of the following (Document date of trial):
         (a) Nucynta ER
         (b) morphine sulfate controlled-release tablets (generic MS Contin)
         (c) Xtampza ER
         (d) For Brand Duragesic requests: fentanyl transdermal patch (generic Duragesic)

      -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

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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 **OxyContin or oxycodone controlled-release (Authorized Generic for OxyContin) and one** of the following**:**

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

i. The patient requires more than or equal to 320 mg/day of controlled-release oxycodone.

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

a. Nucynta ER

b. morphine sulfate controlled-release tablets (specifically generic MS Contin)

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

i. The patient requires less than 320 mg/day of controlled-release oxycodone.

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

a. Nucynta ER

b. morphine sulfate controlled-release tablets (generic MS Contin)

c. Xtampza ER

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 a maximum 90-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.

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**, Nucynta ER, methadone, morphine sulfate controlled-release tablets (generic MS Contin), and Xtampza ER** will be approved based on **ALL** of the following criteria:

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(1) Prescriber attests to **ALL** of 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.
- 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) 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) **ONE** of the following:

i. **ALL** of the following:

a) The patient is being treated for moderate to severe chronic pain that is **non-neuropathic** (examples of neuropathic pain include neuralgias, neuropathies, fibromyalgia)

-AND-

b) 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).[c]

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-OR-

ii. **ALL** of the following:

a) The patient is being treated for moderate to severe n**europathic pain or fibromyalgia**

-AND-

b) 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)

-AND-

c) 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)

b. **Duragesic, fentanyl transdermal (37.5, 62.5, 87.5 mcg/hr), hydromorphone extended-release (generic Exalgo), Hysingla ER, morphine sulfate controlled-release capsules (generic Avinza), morphine sulfate sustained-release capsules (generic Kadian), MS Contin, OxyContin, oxycodone controlled-release (Authorized Generic for OxyContin) oxymorphone extended release** and **Zohydro 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 **ALL** of 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.
- 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-

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(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** (examples of neuropathic pain include neuralgias, neuropathies, fibromyalgia).

-AND-

ii. 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).[c]

-OR-

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

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

-AND-

ii. 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)

-AND-

iii. 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).

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-AND-

(5) The patient has a history of failure, contraindication or intolerance to a trial of **ALL** of the following (Document dates of trial):
1) Nucynta ER
2) morphine sulfate controlled-release tablets (generic MS Contin)
3) Xtampza ER
4) For Brand Duragesic requests: fentanyl transdermal patch (generic Duragesic)

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 a maximum 90-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.

2. Reauthorization

a. **Duragesic, fentanyl transdermal (37.5, 62.5, 87.5 mcg/hr), hydromorphone extended-release (generic Exalgo), Hysingla ER, morphine sulfate controlled-release capsules (generic Avinza), morphine sulfate sustained-release capsules (generic Kadian), methadone, MS Contin, Nucynta ER, OxyContin, oxycodone controlled-release (Authorized Generic for OxyContin), oxymorphone ER Xtampza ER and Zohydro 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

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-AND-

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

- Patient has been screened for substance abuse/opioid dependence
- 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.
- 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 maximum 90-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.

[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 used to treat stage four advanced metastatic cancer or associated conditions (e.g., cancer pain) may be approved based on state mandates.
[c.] For Kentucky business, only a 30-day trial will be required.

3. State of Connecticut Coverage Criteria[a]

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

1. **Fentanyl transdermal (generic Duragesic)** 12, 25, 50, 75, 100 mcg/hr**, methadone, morphine sulfate controlled-release (generic MS Contin), Nucynta ER 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.)

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2. **Morphine sulfate controlled-release capsules (generic Avinza), Duragesic^, fentanyl transdermal patch (37.5, 62.5, 87.5 mcg/hr) ^, Hysingla ER^, hydromorphone extended release (generic Exalgo), morphine sulfate sustained-release capsules (generic Kadian), MS Contin, Oxycontin^, oxycodone controlled-release (authorized generic for OxyContin)^, oxymorphone extended release and Zohydro 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) The patient has a history of failure, contraindication or intolerance to a trial of the following (Document date of trial):
        (a) morphine sulfate controlled-release tablets (generic MS Contin)
        (b) For Brand Duragesic requests: fentanyl transdermal patch (generic Duragesic)

        -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 maximum 90-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.

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

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1. **Fentanyl transdermal (generic Duragesic)** 12, 25, 50, 75, 100 mcg/hr**, methadone, morphine sulfate controlled-release (generic MS Contin), Nucynta ER and Xtampza ER** will be approved based on ALL of the following criteria:

   a. Prescriber attests to **ALL** of 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.
      - 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-

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

   -AND-

   c. Patient has been screened for underlying depression and/or anxiety and if applicable underlying condition has been or is being addressed

   -AND-

   d. **ONE** of the following:

      (1) 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-

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

         i. **ALL** of the following:

            (a) The patient is being treated for moderate to severe chronic pain that is **non-neuropathic** (examples of neuropathic pain include neuralgias, neuropathies, fibromyalgia)

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-AND-

(b) Prior to the start of therapy with the long-acting opioid, the patient has failed a four week trial of a generic short-acting opioid. (Document drug(s) and date of trial).[a]

-OR-

ii. **ALL** of the following:

(a) The patient is being treated for moderate to severe neuropathic pain or fibromyalgia

-AND-

(b) Unless it is contraindicated, the patient has not exhibited an adequate response to 4 weeks of treatment with gabapentin titrated to a therapeutic dose. (Document date of trial) [a]

-AND-

(c) Unless it is contraindicated, the patient has not exhibited an adequate response to 4 weeks of treatment with a generic tricyclic antidepressant titrated to the maximum tolerated dose. (Document drug and date of trial) [a]

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

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

- The information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may

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perform a routine audit and request the medical information necessary to verify the accuracy of the information provided.

- 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** (examples of neuropathic pain include neuralgias, neuropathies, fibromyalgia).

-AND-

ii. Prior to the start of therapy with the long-acting opioid, the patient has failed a four week trial of a generic short-acting opioid. (Document drug(s) and date of trial) [a].

-OR-

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

i. The patient is being treated for moderate to severe neuropathic pain or fibromyalgia

-AND-

ii. Unless it is contraindicated, the patient has not exhibited an adequate response to 4 weeks of treatment with gabapentin titrated to a therapeutic dose. (Document date of trial)[a]

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-AND-

iii. Unless it is contraindicated, the patient has not exhibited an adequate response to 4 weeks of treatment with a generic tricyclic antidepressant titrated to the maximum tolerated dose. (Document drug, and date of trial)[a].

-AND-

(5) The patient has a history of failure, contraindication or intolerance to a trial of the following (Document date of trial)[a]:
(a) morphine sulfate controlled-release tablets (generic MSContin)
(b) For Brand Duragesic requests: fentanyl transdermal patch (generic Duragesic)

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 <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 maximum 90-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.

2. Reauthorization

a. **Hydromorphone extended-release (generic Exalgo), Duragesic^, fentanyl transdermal patch (37.5, 62.5, 87.5 mcg/hr)^, Hysingla ER^, methadone, morphine sulfate controlled-release capsules (generic Avinza), morphine sulfate sustained-release capsules^ (generic Kadian) MS Contin, Nucynta ER , OxyContin^, oxycodone controlled-release (Authorized Generic for OxyContin)^, oxymorphone extended release, Xtampza ER and Zohydro ER^ [Applies to all brand and generic versions of listed products)]** will be reauthorized based on 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-

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

-AND-

(3) Prescriber attests to **ALL** of 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.
- 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 maximum 90-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.

[a.] For Connecticut only a trial/failure of generic medications is required. Trial may not be more than 60 days.

4. Coverage Criteria for the State of Florida:

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

1. **Fentanyl transdermal (generic Duragesic)** 12, 25, 50, 75, 100 mcg/hr**, methadone, morphine sulfate controlled-release tablets (generic MS Contin), Nucynta ER 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.)

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2. **Duragesic^, fentanyl transdermal (37.5, 62.5, 87.5 mcg/hr)^, hydromorphone extended release (generic Exalgo), Hysingla ER^, morphine sulfate controlled-release capsules (generic Avinza), morphine sulfate sustained release capsules^ (generic Kadian), MS Contin, Oxycontin^, oxycodone controlled-release^ (Authorized Generic for Oxycontin), oxymorphone extended release^ and Zohydro 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)]** 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) The patient has a history of failure, contraindication or intolerance to a trial of the following: (Document date of trial).
         (a) Xtampza ER
         (b) For Brand Duragesic requests: fentanyl transdermal patch (generic Duragesic)

      -OR-

      (2) If request is for Oxycontin or oxycodone controlled-release (Authorized generic for OxyContin) the patient requires more than 320 mg/day of controlled-release oxycodone.

      -OR-

      (3) 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 maximum 90-day authorization may be authorized one time

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for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.

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

1. Initial Authorization

a. **Fentanyl transdermal** 12, 25, 50, 75, 100 mcg/hr**, methadone, morphine sulfate controlled-release tablets (generic MS Contin), Nucynta ER and Xtampza ER** will be approved based on the following criteria:

(1) Prescriber attests to **ALL** of 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.
- 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) 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:

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i. The patient is being treated for moderate to severe chronic pain that is **non-neuropathic** (examples of neuropathic pain include neuralgias, neuropathies, fibromyalgia).

-AND-

ii. 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-

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

i. The patient is being treated for moderate to severe n**europathic pain or fibromyalgia**

-AND-

ii. 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)

-AND-

iii. 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).

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

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

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- 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.
- 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** (examples of neuropathic pain include neuralgias, neuropathies, fibromyalgia)

-AND-

ii. 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).

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

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

-AND-

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ii. 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)

-AND-

iii. 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)

(5) The patient has a history of failure, contraindication or intolerance to a trial of **BOTH** of the following (Document dates of trial):
(a) Xtampza ER.
(b) For Brand Duragesic requests: fentanyl transdermal patch (generic Duragesic)

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 maximum 90-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.

2. Reauthorization

a. **Duragesic^, fentanyl transdermal (37.5, 62.5, 87.5 mcg/hr)^, hydromorphone extended-release, Hysingla ER^, methadone, morphine sulfate controlled-release capsules (generic Avinza), morphine sulfate sustained-release capsules^ (generic Kadian) MS Contin, Nucynta ER, Oxycontin^, oxycodone controlled-release^ (Authorized Generic for Oxycontin), oxymorphone extended release, Xtampza ER** and **Zohydro 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)

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-AND-

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

-AND-

(3) Prescriber attests to **ALL** of 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.
- 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 maximum 90-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.

5. Coverage Criteria for State of Maryland[a]

A. Cancer or End of Life (define as a < 2 year life expectancy) related pain

1. **Fentanyl transdermal (generic Duragesic)** 12, 25, 50, 75, 100 mcg/hr**, methadone, Xtampza ER, Nucynta ER and, morphine sulfate controlled-release tablet (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. **Duragesic^ fentanyl transdermal** (37.5, 62.5, 87.5 mcg/hr)^, **hydromorphone extended release (generic Exalgo), Hysingla ER^, morphine sulfate controlled-release capsules (generic Avinza), morphine sulfate sustained release capsules^ (generic Kadian), MS Contin,**

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oxymorphone extended release^ and Zohydro ER^ [Applies to all brand and generic versions of listed products except generic fentanyl transdermal (generic Duragesic) and generic morphine sulfate controlled-release tablets (generic MS Contin) 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) The patient has a history of failure, contraindication or intolerance to a trial of at least **three** of the following (Document drug name and date of trial):
      (a) Nucynta ER
      (b) morphine sulfate controlled-release tablets (generic MS Contin)
      (c) Xtampza ER
      (d) For Brand Duragesic requests: fentanyl transdermal patch (generic Duragesic) (Must be one of the three trials)

   -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 **OxyContin or oxycodone controlled-release (Authorized Generic for OxyContin) and o0ne** of the following**:**

   (a) both of the following:
      i. The patient requires more than or equal to 320 mg/day of controlled-release oxycodone.
      ii. The patient has a history of failure, contraindication or intolerance to **BOTH** of the following (Document date of trial):
         a. Nucynta ER

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b. morphine sulfate controlled-release tablets (specifically generic MS Contin)

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

i. The patient requires less than 320 mg/day of controlled-release oxycodone.
ii. The patient has a history of failure, contraindication or intolerance to **ALL** of the following (Document date of trial):
a. Nucynta ER
b. morphine sulfate controlled-release tablets (generic MS Contin)
c. Xtampza ER

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 maximum 90-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.

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

1. Initial Authorization

a. **Fentanyl transdermal (generic Duragesic)** 12, 25, 50, 75, 100 mcg/hr**, Xtampza ER, Nucynta ER, methadone and morphine sulfate controlled-release (generic MS Contin)** will be approved based on the following criteria:

(1) Prescriber attests to **ALL** of 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.
- 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-

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(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.

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

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

i. **ALL** of the following:

a) The patient is being treated for moderate to severe chronic pain that is **non-neuropathic** (examples of neuropathic pain include neuralgias, neuropathies, fibromyalgia).

-AND-

b) 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-

ii. **ALL** of the following:

a) The patient is being treated for moderate to severe n**europathic pain or fibromyalgia**

-AND-

b) 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)

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-AND-

c) 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)

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

(1) Prescriber attests to **ALL** of 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.
- 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:

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

i. The patient is being treated for moderate to severe chronic pain that **is non-neuropathic** (examples of neuropathic pain include neuralgias, neuropathies, fibromyalgia).

-AND-

ii. 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) **ALL** of the following:

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

-AND-

ii. 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)

-AND-

iii. 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).

-AND-

(5) The patient has a history of failure, contraindication or intolerance to a trial of at least **three** of the following: (Document date of trial):
a) Nucynta ER
b) morphine sulfate controlled-release tablets (specifically generic MS Contin)
c) Xtampza ER
d) For Brand Duragesic requests: fentanyl transdermal patch (generic Duragesic) (Must be one of the three trials)

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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 maximum 90-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.

2. **Reauthorization**
   a. **Duragesic, fentanyl transdermal** (37.5, 62.5, 87.5 mcg/hr)**, hydromorphone extended-release, Hysingla ER, methadone, morphine sulfate controlled-release capsules (generic Avinza), morphine sulfate sustained-release capsules (generic Kadian) MS Contin, Nucynta ER, OxyContin, oxycodone controlled-release (Authorized Generic for OxyContin), Oxymorphone ER, Xtampza ER** and **Zohydro ER [Applies to all brand and generic versions of listed products]** will be reauthorized based on 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 **ALL** of 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.
      - 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)

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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 <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 reauthorization criteria requirements for long-acting opioids, a denial should be issued and a maximum 90-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.

[a.] State mandates may apply. Any federal regulatory requirements and the patient specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

6. Coverage Criteria for the State of West Virginia[a]

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

1. **Hysingla ER, fentanyl transdermal (generic Duragesic)** 12, 25, 50, 75, 100 mcg/hr**, methadone, morphine sulfate controlled-release tablet (generic MS Contin), Xtampza ER, Nucynta 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. **Duragesic, fentanyl transdermal** (37.5, 62.5, 87.5 mcg/hr)^**, hydromorphone extended-release (generic Exalgo), morphine sulfate controlled-release capsules (generic Avinza), morphine sulfate sustained release capsules^ (generic Kadian), MS Contin, OxyContin^, oxycodone controlled-release (Authorized Generic for OxyContin)^, oxymorphone extended-release, and Zohydro ER^ [Applies to all brand and generic versions of listed products except generic fentanyl transdermal (generic Duragesic) and generic morphine sulfate controlled-release tablets (generic MS Contin)]** will be approved based on <u>**ALL**</u> 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-

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b. **ONE** of the following:

(1) The patient has a history of failure, contraindication or intolerance to a trial of the following (Document date of trial):
(a) Xtampza ER
(b) For Brand Duragesic requests: fentanyl transdermal patch (generic Duragesic)

-OR-

(2) For **OxyContin^ and oxycodone controlled-release (Authorized Generic for OxyContin)^** the patient requires more than 320 mg/day of controlled-release oxycodone.

-OR-

(3) 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 maximum 90-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.

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

1. Initial Authorization

a. **Fentanyl transdermal (generic Duragesic)** 12, 25, 50, 75, 100 mcg/hr**, Hysingla ER, methadone, morphine sulfate controlled-release tablet (specifically generic MS Contin), Xtampza ER, and Nucynta ER** will be approved based on the following criteria:

(1) Prescriber attests to **ALL** of 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.

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- 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) 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) **ONE** of the following:

i. **ALL** of the following:

a) The patient is being treated for moderate to severe chronic pain that is **non-neuropathic** (examples of neuropathic pain include neuralgias, neuropathies, fibromyalgia).

-AND-

b) 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-

ii. **ALL** of the following:

a) The patient is being treated for moderate to severe n**europathic pain or fibromyalgia**

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-AND-

b) 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)

-AND-

c) 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).

b. **Duragesic^, fentanyl transdermal** (37.5, 62.5, 87.5 mcg/hr)^, **hydromorphone extended-release, morphine sulfate controlled-release capsules (generic Avinza), morphine sulfate sustained-release capsules^ (generic Kadian), MS Contin, OxyContin^, oxycodone controlled-release (Authorized Generic for OxyContin)^, oxymorphone extended-release and Zohydro ER^ [Applies to all brand and generic versions of listed products except generic fentanyl transdermal (generic Duragesic) and generic morphine sulfate controlled-release tablets (generic MS Contin)]** will be approved based on **ALL** of the following criteria:

(1) Prescriber attests to **ALL** of 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.
- 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-

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(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** (examples of neuropathic pain include neuralgias, neuropathies, fibromyalgia)

-AND-

ii. 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) **ALL** of the following:

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

-AND-

ii. 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)

-AND-

iii. 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).

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

(a) Xtampza ER

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(b) For Brand Duragesic requests: fentanyl transdermal patch (generic Duragesic)

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 <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 maximum 90-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.

2. Reauthorization

a. **Duragesic, fentanyl transdermal** (37.5, 62.5, 87.5 mcg/hr)**, hydromorphone extended-release (generic Exalgo), Hysingla ER, methadone, morphine sulfate controlled-release capsules (generic Avinza), morphine sulfate sustained-release capsules (generic Kadian) MS Contin, Nucynta ER, OxyContin, oxycodone controlled-release (Authorized Generic for OxyContin), oxymorphone extended-release, Xtampza ER, and Zohydro ER^ [Applies to all brand and generic versions of listed products] will be approved based on <u>ALL</u> 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>ALL</u>** of 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.
- Patient has been screened for substance abuse/opioid dependence

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- 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 maximum 90-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.

[a.] State mandates may apply. Any federal regulatory requirements and the patient specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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.

   [^]Duragesic, Hysingla ER, fentanyl 37.5, 62.5 and 87.5 mcg/hr, Kadian (brand and generic), 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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7. Duragesic [Package Insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc. March 2021.

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11. Spatar, SB. Standardizing the use of mental health screening instruments in patients with pain. Fed Pract. 2019 Oct; 36 (Suppl 6): S28-S30
12. Sullivan MD. Depression effects on long-term prescription opioid use, abuse, and addiction. Clin J Pain. 2018 Sep;34(9):878-884.

Program	Prior Authorization/Medical Necessity - Long-Acting Opioid Pain Medications
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.

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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 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.

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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 screening for underlying depression and anxiety to Maryland non-cancer/EOL initial authorization. Revised duration of trial for Connecticut mandates.

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