



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2021 P 3053-13 |
| Program | Step Therapy – Long Acting Opioids |
| Medication | Includes both brand and generic versions of the listed products unless otherwise noted: Duragesic brand only [^] , hydromorphone extended-release (generic Exalgo), fentanyl transdermal patch (37.5, 62.5, 87.5 mcg/hr) [^] , Hysingla ER [^] (hydrocodone extended-release [^]), morphine sulfate controlled-release capsules [^] (generic Kadian), morphine controlled-release capsules (generic Avinza) [^] , MS Contin brand only, oxycodone controlled-release (authorized generic of OxyContin) [^] , OxyContin [^] (oxycodone controlled-release [^]), oxymorphone hcl extended-release (generic Opana ER), and Zohydro ER [^] (hydrocodone extended-release) |
| P&T Approval Date | 2/2015, 10/2015, 8/2016, 1/2017, 5/2017, 7/2017, 4/2018, 9/2018, 9/2019, 12/2019, 4/2020, 5/2021 |
| Effective Date | 8/1/2021; Oxford: N/A |

1. Background:

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. Long-acting opioid analgesics including morphine sulfate controlled-release capsules, Duragesic (including fentanyl transdermal), hydromorphone ER, Hysingla ER, morphine sulfate sustained-release capsules, MS Contin, Nucynta ER, oxycodone 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 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.



Section Overview

Section 2. Coverage Criteria for the Book of Business

Section 3. Coverage Criteria for the State of Maryland

Section 4. Coverage Criteria for the State of Florida and West Virginia

2. Coverage Criteria^{a, b}:

A. morphine sulfate controlled-release capsules (generic Avinza)[^], Duragesic[^], hydromorphone extended-release (generic Exalgo), fentanyl transdermal (37.5, 62.5, 87.5 mcg/hr)[^] Hysingla ER[^], morphine sulfate sustained release capsules[^] (generic Kadian), MS Contin (brand only), Oxycontin[^], oxycodone controlled-release[^], generic 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 generic Duragesic] will be approved based on **BOTH of the following criteria:**

1. **One** of the following:

a. The patient has a history of failure, contraindication or intolerance to a trial of **ALL** of the following^b:

- (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)

-OR-

b. 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.

-AND-

2. Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided.

Authorization will be issued for 12 months. If member has cancer-related or end of life pain the authorization will be issued for 24 months.

- ^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply
- ^b State of Connecticut must try morphine sulfate controlled release tablets (generic MS Contin) only.
- ^c 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.

3. Coverage Criteria for State of Maryland^a:

A. morphine sulfate controlled-release capsules (generic Avinza), Duragesic[^], hydromorphone extended release (generic Exalgo), fentanyl transdermal (37.5, 62.5, 87.5 mcg/hr)[^] Hysingla ER[^], morphine sulfate sustained-release capsules[^] (generic Kadian), MS Contin (brand only), generic oxymorphone extended-release, OxyContin[^], oxycodone controlled-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 generic Duragesic] will be approved based on **BOTH of the following criteria:**

1. **One** of the following:

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

-OR-

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

-AND-

2. Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided.

Authorization will be issued for 12 months. If member has cancer-related or end of life pain the authorization will be issued for 24 months.

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

4. Coverage Criteria for State of Florida and West Virginia^a

A. **morphine sulfate controlled-release capsules (generic Avinza), Duragesic[^], hydromorphone extended-release (generic Exalgo), fentanyl transdermal (37.5, 62.5, 87.5 mcg/hr)[^], Hysingla ER^{^b}, morphine sulfate sustained-release capsules[^] (generic Kadian), MS Contin (brand only), OxyContin[^], oxycodone controlled-release[^], generic 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 generic Duragesic] will be approved based on BOTH of the following criteria:**

a. **ONE** of the following:

(1) The patient has a history of failure, contraindication or intolerance to a trial of Xtampza ER.

-OR-

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

-AND-

b. Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided.

Authorization will be issued for 12 months. If member has cancer-related or end of life pain the authorization will be issued for 24 months.

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

^b For West Virginia, Hysingla ER is not excluded from coverage.

[^] Duragesic (brand only), fentanyl transdermal (37.5, 62.5, 87.5 mcg/hr), Hysingla ER, morphine sulfate sustained-release capsules (generic Kadian), oxycodone controlled-release (authorized generic for OxyContin), OxyContin and Zohydro ER are typically excluded from coverage. Tried/Failed criteria may be in place. Please refer to plan specifics to determine exclusion status.

5. Additional Clinical Programs:

- Prior Authorization/Medical Necessity criteria and supply limits may also be in place.
- Supply Limits may be in place.
- 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.

6. References:

1. Hydromorphone extended release [Package Insert]. Webster Grover, MO: Mallinckrodt, Inc.; January 2021. Hysingla ER [package insert]. Stanford, CT: Purdue Pharma; March 2021.
2. MS Contin [package insert]. Stanford, CT. Purdue Pharma; March 3201
3. Nucynta ER [package insert]. Stoughton, MA: Collegium Pharmaceuticals, Inc. March 2021.
4. Oxymorphone Extended Release [package insert]. Brookhaven, NY. Amneal Pharmaceuticals of NY; April 2021..
5. OxyContin [package insert]. Stanford, CT: Purdue Pharma; March 2021.
6. Zohydro ER [package insert]. Princeton, NJ: Perison Therapeutics; March 2021.
7. Xtampza ER [package insert]. Cincinnati, OH: Patheon Pharmaceuticals. March 2021.
8. Duragesic [Package Insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc. March 2021.
9. Fentanyl Patch [Package Insert}. Hazelwood, MO: Mallinckrodt, Inc. March 2021.
10. Morphine sulfate extended release capsule [Package Insert]. Coventry, RI: Rhodes Pharmaceuticals L.P.; March 2021.
11. Morphine extended-release {Package Insert}. Bridgewater, NJ: Amneal Pharmaceuticals LLC; January 2020.
12. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016. JAMA. Published online March 2016.

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| Program | Step Therapy - Long Acting Opioids |
| Change Control | |
| 2/2015 | New program. |

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| 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 age limit to criteria. Added Maryland specific criteria and Continuation of Care. Added Maine specific criteria. |
| 8/2016 | Added Xtampza ER as a preferred product. With addition of Xtampza ER, removed specific requirements for state of Maine. Added provider attestation. Updated references. |
| 11/2016 | Added California coverage information. |
| 1/2017 | Updated criteria to require a trial and failure of Xtampza ER prior to approval of OxyContin or oxycodone extended-release. |
| 5/2017 | Updated criteria to differentiate between oxycodone controlled-release (authorized generic for OxyContin) and Xtampza ER (oxycontin extended-release). Removed Opana ER as a step through product. Added Arymo ER. |
| 7/2017 | Added Morphabond ER, Troxyca ER, and Vantrela ER to the criteria. Added end of life pain to reference of cancer pain. Removed fentanyl transdermal as a step one option. Updated references. |
| 4/2018 | Added Duragesic and fentanyl transdermal to the criteria. Updated state mandates for Connecticut. |
| 9/2018 | Removed Troxyca and Vantrela. Combined Oxycontin section. Added authorization for cancer/end-of-life. |
| 9/2019 | Added step for brand Duragesic requiring trial of generic. |
| 12/2019 | Removed Embeda from criteria due to market removal. Moved Arymo ER to first step for Maryland and West Virginia. |
| 4/2020 | Added state mandate for metastatic cancer use. Updated references. |
| 5/2021 | Annual review. Updated references. Removed products no longer available. |