



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 3053-9
Program	Step Therapy – Long Acting Opioids
Medication	Includes both brand and generic versions of the listed products unless otherwise noted: Arymo ER^ (morphine extended-release tablets), Avinza^ (morphine extended-release capsules), Duragesic brand only^, Embeda^ (morphine sulfate and naltrexone), Exalgo^ (hydromorphone extended-release), fentanyl transdermal patch (37.5, 62.5, 87.5 mcg/hr)^, Hysingla ER^ (hydrocodone extended-release), Kadian^ (morphine sulfate sustained-release capsules), Morphabond ER^ (morphine sulfate extended-release), MS Contin brand only, OxyContin^ (oxycodone controlled-release^), oxymorphone hcl extended-release (generic only), 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
Effective Date	12/1/2018; Oxford: 12/1/2018

1. Background:

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. Long-acting opioid analgesics including Arymo ER, Avinza, Duragesic (including fentanyl transdermal), Embeda, Exalgo, hydromorphone ER, Hysingla ER, Kadian, Morphabond ER, MS Contin, Nucynta ER, Opana 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:

A. Arymo ER[^], Avinza[^], Duragesic[^], Embeda[^], Exalgo[^], fentanyl transdermal (37.5, 62.5, 87.5 mcg/hr)[^] Hysingla ER[^], Morphabond ER[^], 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 **ALL 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 (specifically generic MS Contin)
- (3) Xtampza ER

-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.

3. Coverage Criteria for State of Maryland^a:

- A. **Arymo ER[^], Avinza[^], Duragesic[^], Exalgo[^], fentanyl transdermal (37.5, 62.5, 87.5 mcg/hr)[^] Hysingla ER[^], Kadian[^], Morphabond ER[^], 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 **ALL** 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 (specifically generic MS Contin)
 - (3) Embeda
 - (4) Xtampza ER

-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. Arymo ER[^], Avinza[^], Duragesic[^], Embeda^{^b}, Exalgo[^], fentanyl transdermal (37.5, 62.5, 87.5 mcg/hr)[^] Hysingla ER[^], Kadian[^], Morphabond ER[^], 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 ALL 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, Embeda and Hysingla ER are not excluded from coverage.

5. Additional Clinical Programs:

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

- Supply Limits may be in place.

^Arymo ER, Avinza (brand only), Duragesic (brand only), Embeda, Exalgo (brand only), fentanyl transdermal (37.5, 62.5, 87.5 mcg/hr), Hysingla ER, Morphabond ER, 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.

6. References:

1. Avinza Prescribing Information. Pfizer, Inc. April 2014.
2. Embeda Prescribing Information. Pfizer Inc. October 2014.
3. Exalgo Prescribing Information. Mallinckrodt, Inc. June 2015.
4. Hysingla ER Prescribing Information. Purdue Pharma. February 2015.
5. Kadian Prescribing Information. Actavis Elizabeth LLC. April 2014.
6. MS Contin Prescribing Information. Purdue Pharma. June 2014.
7. Nucynta ER Prescribing Information. Janssen Pharmaceuticals. April 2014.
8. Opana ER Prescribing Information. Endo Pharmaceuticals. October 2017.
9. OxyContin Prescribing Information. Purdue Pharma, August 2015.
10. Xtampza ER prescribing information. Collegium Pharmaceuticals, Inc. April 2016.
11. Zohydro ER Prescribing Information. Pernix Therapeutics. January 2016.
12. Chou, Roger, Amir Quaseem, Vincenza Snow, Donald Casey, Thomas Cross Jr., Paul Shekelle, and Douglas Owens. Clinical Guidelines: Diagnosis and Treatment of Low Back Pain: a Joint Clinical Practice Guideline From the American College of Physicians and the American Pain Society. *Annals of Internal Medicine* 2007;147: 478-491. 20 May 2008 <www.annals.org>.
13. "WHO's Pain Ladder." World Health Organization Cancer. World Health Organization. 30 May 2008 <www.who.int/cancer/palliative/painladder/en/>.
14. "NCCN Practice Guidelines in Oncology." NCCN Practice Guidelines in Oncology - V.1.2008 Adult Cancer Pain. 6 May 2008. National Comprehensive Cancer Network. 02 June 2008 <http://www.nccn.org/professionals/physician_gls/PDF/pain.pdf>.
15. Veterans Health Administration, Department of Defense. VA/DoD clinical practice guideline for management of opioid therapy for chronic pain. Washington (DC): Veterans Health Administration, Department of Defense;2003.
16. Trescot AM, Boswell MV, Atluri SL, Hansen HC, et al. Opioid Guidelines in the management of Chronic Non-Cancer Pain. *Pain Physician*. 2006;9:1-40.
17. Franklin GM. Opioids for chronic noncancer pain. A position paper of the American Academy of Neurology. *Neurology*. 2014;83:1277-1284.
18. Rosenquist EWK. Overview of the treatment of chronic pain. UptoDate. October 2014. http://www.uptodate.com/contents/overview-of-the-treatment-of-chronic-pain?source=search_result&search=long+acting+opioids&selectedTitle=1%7E150#H1
19. Argoff CE, Silvershein DI. A Comparison of Long- and Short-Acting Opioids for the Treatment of Chronic Noncancer Pain: Tailoring Therapy to Meet Patient Needs. *Mayo Clin Proc*. 2009;84(7):602-612.



20. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016. JAMA. Published online March 15, 2016.
21. Arymo ER prescribing information. Egalet US Inc. January 2017.
22. Morphabond ER prescribing information. Daiichi Sankyo Inc. April 2017.
23. Fentanyl Patch prescribing information. Mallinckrodt, Inc. Hazelwood, MO. October 2014.

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