

Opioid Management/Long Acting Oral Opioid Step Therapy

Policy # 00323

Original Effective Date: 11/16/2011

Current Effective Date: 01/13/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member’s contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

For Patients With “Prior Authorization” ONLY OR BOTH “Prior Authorization” and “Step Therapy”:

Short Acting Oral/Rectal Opioids

Based on a review of the available data, the Company may consider short acting oral/rectal opioids [including, but not limited to acetaminophen/caffeine/dihydrocodeine products (generics, Synalgos DC^{®†}, Trezix^{®†}), acetaminophen/codeine products (generics, Tylenol^{®†} with Codeine), belladonna/opium, carisoprodol compound/codeine, carisoprodol/aspirin/codeine, codeine, meperidine products (generics, Demerol^{®†}), hydromorphone products (generics, Dilaudid^{®†}), oxycodone products (generics, Oxaydo^{®†}, Oxecta^{™†}, Roxicodone^{®†}, RoxyBond^{™†}), oxycodone/ibuprofen, oxycodone/acetaminophen products (generics, endocet^{®†}, Magnacet^{®†}, Percocet^{®†}, Primlev^{®†}, roxicet^{™†}, Nalocet^{®†}, Xolox^{®†}), oxycodone/aspirin products (generics, Endodan^{®†}, Percodan^{®†}), hydrocodone/acetaminophen products (generics, Hycet^{®†}, lorcet^{®†}, Lortab^{®†}, Norco^{®†}, verdrocet^{®†}, vicodin^{®†}, vicodin^{®†} ES, vicodin^{®†} HP, Xodol^{®†}, zamicet^{®†}, Zydone^{®†}, Maxidone^{®†}, lorcet^{®†} HD, lorcet^{®†} plus), hydrocodone/ibuprofen products (generics, Ibudone^{®†}, reprevain^{®†}, Vicoprofen^{®†}, xylon^{®†}), levorphanol, morphine sulfate, Nucynta^{®†} (tapentadol), oxymorphone products (generics, Opana^{®†}), butalbital containing products (aspirin/butalbital/caffeine/codeine, ascomp^{®†} with codeine, butalbital compound/codeine, acetaminophen/butalbital/caffeine/codeine, Fioricet^{®†} with Codeine, Fiorinal^{®†} with Codeine) or aspirin/caffeine/dihydrocodeine] to be **eligible for coverage**** when the below patient selection criteria are met:

Patient Selection Criteria:

Coverage eligibility will be considered for short acting oral/rectal opioids (EXCEPT levorphanol 2 mg and 3 mg tablets) in prescription fills with quantities greater than a 7 day supply OR prescription fills with quantities greater than a cumulative 21 day supply within a 60 day period when the following criteria are met:

- Requested opioid is utilized to treat cancer pain; OR
- Requested opioid is utilized for end of life care; OR

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- ALL of the following are met:
 - Prescriber certifies that there is an active treatment plan, which includes the use of other pharmacological and non-pharmacological agents for pain relief (as appropriate), in place for the member; AND
 - Prescriber certifies that there is an agreement between the patient and the prescriber, documented in the medical record, which addresses the issues of prescription management, diversion, doctor/pharmacy shopping, and the use of other substances; AND
 - Prescriber has completed an addiction risk assessment.

Coverage eligibility will be considered for levorphanol 2 mg and 3 mg tablets when the following criteria are met:

- Patient has tried and failed (e.g., intolerance or inadequate response) TWO of the following SHORT ACTING opioid products unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient. SHORT ACTING products for trial and failure include: GENERIC acetaminophen with codeine #3/#4, GENERIC belladonna/opium, GENERIC carisoprodol compound with codeine, GENERIC carisoprodol/aspirin/codeine, GENERIC codeine tablets, GENERIC endocet, GENERIC hydrocodone/acetaminophen, GENERIC hydrocodone/ibuprofen, GENERIC hydromorphone immediate release, GENERIC lorcet, GENERIC meperidine, GENERIC morphine sulfate immediate release, Nucynta immediate release, GENERIC oxycodone immediate release, GENERIC oxycodone/aspirin, GENERIC oxycodone/ibuprofen, GENERIC oxycodone/acetaminophen, GENERIC oxymorphone immediate release, GENERIC vicodin, GENERIC vicodin ES, GENERIC Vicodin HP, GENERIC lorcet HD, GENERIC lorcet plus, GENERIC aspirin/butalbital/caffeine/codeine, GENERIC butalbital/compound with codeine, GENERIC ascomp with codeine, GENERIC aspirin/caffeine/dihydrocodeine, and GENERIC acetaminophen/butalbital/caffeine/codeine; AND
- Patient meets ONE of the following:
 - Requested opioid is utilized to treat cancer pain; OR
 - Requested opioid is utilized for end of life care; OR
 - ALL of the following are met:
 - Prescriber certifies that there is an active treatment plan, which includes the use of other pharmacological and non-pharmacological agents for pain relief (as appropriate), in place for the member; AND
 - Prescriber certifies that there is an agreement between the patient and the prescriber, documented in the medical record, which addresses the issues of prescription management, diversion, doctor/pharmacy shopping, and the use of other substances; AND
 - Prescriber has completed an addiction risk assessment.



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When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of short acting oral/rectal opioids (mentioned above, EXCEPT levorphanol 2 mg and 3 mg tablets) in prescription fills with quantities greater than a 7 day supply OR prescription fills with quantities greater than a cumulative 21 day supply within a 60 day period when patient selection criteria are not met to be **not medically necessary.****

Based on review of available data, the Company considers the use of levorphanol 2 mg and 3 mg tablets when patient selection criteria are not met to be **not medically necessary.****

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Long Acting Oral/Transdermal Opioids

Based on a review of the available data, the Company may consider long acting oral/transdermal opioids [including, but not limited to buprenorphine patch/film products (Butrans[®]‡, Belbuca[™]‡), fentanyl patch products (generics, Duragesic[®]‡), hydromorphone ER products (generics, Exalgo[™]‡), hydrocodone products (generics, Hysingla[™]‡, Zohydro[®]‡ ER), methadone products (generics, methadose[™]‡, Dolophine[®]‡), morphine sulfate products (generics, Arymo[™]‡ ER, Kadian[®]‡, Morphabond[™]‡ ER, MS Contin[®]‡, Oramorph SR[™]‡), Embeda[™]‡ (morphine/naltrexone), oxycodone products (Branded Oxycodone, Oxycontin[®]‡, Xtampza[™]‡ ER), oxymorphone products (generics, Opana[®]‡ ER), Xartemis[®]‡ XR (oxycodone/acetaminophen), and Nucynta[®]‡ ER (tapentadol)] to be **eligible for coverage**** when the below patient selection criteria are met:

Patient Selection Criteria:

Coverage eligibility will be considered for long acting oral/transdermal opioids when the following criteria are met:

- Requested opioid is utilized to treat cancer pain; OR
- Requested opioid is utilized for end of life care; OR



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- ALL of the following are met:
 - Patient requires around the clock pain control; AND
 - Prescriber certifies that there is an active treatment plan, which includes the use of other pharmacological and non-pharmacological agents for pain relief (as appropriate), in place for the member; AND
 - Prescriber certifies that there is an agreement between the patient and the prescriber, documented in the medical record, which addresses the issues of prescription management, diversion, doctor/pharmacy shopping, and the use of other substances; AND
 - Prescriber has completed an addiction risk assessment; AND
- If the requested drug is Arymo ER, Hysingla ER, Dolophine, Duragesic Patch, Embeda, Exalgo, Kadian, MS Contin, Nucynta ER, Opana ER, Branded Oxycodone ER, Xartemis XR, Xtampza ER, Zohydro ER, generic hydrocodone bitartrate ER CAPS, fentanyl patch (37.5, 62.5 and 87.5 mcg), or Morphabond ER:
 - Patient has tried and failed at least TWO of the following long acting opioids: Belbuca, generic buprenorphine patch (5 mcg, 7.5 mcg, 10 mcg, 15 mcg, 20 mcg), generic fentanyl patch (12 mcg, 25 mcg, 50 mcg, 75 mcg, 100 mcg), generic hydromorphone ER, generic hydrocodone bitartrate ER TABS, generic methadone, generic methadose, generic morphine sulfate ER, generic morphine sulfate CR, or Oxycontin unless there is clinical evidence or patient history that suggests the use of TWO of the mentioned long acting opioid alternatives will be ineffective or cause an adverse reaction to the patient; AND
- If the requested drug is Butrans Patch (5 mcg, 7.5 mcg, 10 mcg, 15 mcg, 20 mcg):
 - Patient has tried and failed generic buprenorphine patch (5 mcg, 7.5 mcg, 10 mcg, 15 mcg, 20 mcg) AND patient has tried and failed Belbuca unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of long acting oral/transdermal opioids (mentioned above) when the patient selection criteria are not met to be **not medically necessary**.**



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When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

For Patients With "Step Therapy" (generic before brand) ONLY:

(Note: Applies only to Self-Funded Groups)

Based on a review of the available data, brand name oral long acting opioid products [including, but not limited to Arymo ER (morphine sulfate), Morphabond ER (morphine sulfate), Embeda (morphine/naltrexone), Exalgo (hydromorphone), Kadian (morphine sulfate), MS Contin (morphine sulfate), Nucynta ER (tapentadol), Opana ER (oxymorphone), Oramorph SR (morphine sulfate), Zohydro ER (hydrocodone), Xtampza ER (oxycodone), and Branded Oxycodone ER] may be considered **eligible for coverage**** when one of the below patient selection criteria is met:

Patient Selection Criteria:

Coverage eligibility will be considered for brand name oral long acting opioid products when ONE of the following criteria is met:

- Requested drug is any of the brand name long acting oral opioids and patient has tried and failed generic hydromorphone ER, generic morphine sulfate CR, generic morphine sulfate ER, or generic oxymorphone ER; OR
- Requested drug is Xtampza ER, Branded Oxycodone ER, Nucynta ER, Exalgo, or Zohydro ER and patient is unable to tolerate morphine sulfate or has a drug allergy to morphine sulfate; OR
- Requested drug is Xtampza ER, Branded Oxycodone ER, Nucynta ER, Exalgo, or Zohydro ER and patient has renal insufficiency; OR
- There is clinical evidence or patient history that suggests the generically available products will be ineffective or cause an adverse reaction to the patient.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of brand name oral long acting opioids when patient selection criteria are not met or for usage not included in the above patient selection criteria to be **not medically necessary.****



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Background/Overview

Opioid Management

It's a well-known fact that opioid overuse and abuse has reached epidemic proportions in our state. In fact, Louisiana has the sixth highest opioid prescription per-capita rate, making the state one of only eight states that have more opioid prescriptions dispensed in a year than they have residents. More than 800 Louisiana residents died from overdoses of both prescription and illicit opioids in 2015.

Long Acting Opioid Step Therapy

Opioid analgesics have a central role in the management of moderate to severe pain. These medications produce most of their effects by binding to μ , κ , and δ receptors in the central nervous system (CNS). However, tapentadol extended-release has a unique dual mechanism of action. It demonstrates μ -opioid agonist activity and inhibition of norepinephrine reuptake. Sustained-release opioid dosage forms offer a long duration of effect, reduce severity of end-of-dose pain, and allow many patients to sleep through the night. All of the available long acting oral opioids share the same general indication. Although there are differences noted in some studies, it is generally accepted that these drugs are equally safe and effective when administered at equipotent doses.

Morphine undergoes conjugation in the liver to two primary metabolites. Significant concentrations of these metabolites result from morphine's extensive first-pass metabolism. Accumulation of these metabolites, primarily in renally impaired patients, may be associated with adverse effects such as hyperalgesia, myoclonus, and prolonged respiratory depression. Although a dosage reduction of morphine for renally impaired patients has been proposed, this recommendation has not been firmly established. When other safer opioids are available, it is recommended to avoid the use of morphine in patients with renal dysfunction. Oxycodone is extensively metabolized to noroxycodone, oxymorphone, and their glucuronides. Noroxycodone is a much weaker analgesic than oxycodone, and oxymorphone is present in low concentrations in the plasma. Therefore, the parent compound is primarily responsible for the opioid activity. In the presence of renal dysfunction, the elimination half-life of the parent compound is lengthened, and the excretion of metabolites is severely impaired, so that accumulation can occur. Oxycodone should be given cautiously in the setting of renal impairment and use of oxycodone in patients with a creatinine clearance of < 60 mL/min should be avoided. Oxymorphone is highly metabolized and has two major metabolites. Oxymorphone accumulates in renal failure. Hydromorphone is minimally metabolized by P450 enzymes. There is no evidence that hydromorphone inhibits or induces any enzymes. The dosage of hydromorphone should be adjusted in renal failure. Tapentadol is minimally metabolized by CYP enzymes. The major pathway of metabolism is conjugation with glucuronic acid to produce glucuronides. None of the metabolites contribute to the analgesic activity.



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Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Regarding the opioid management criteria, Blue Cross Blue Shield of Louisiana developed this policy after considering a breadth of clinical guidelines, industry best practices, state regulatory requirements and our own member population in order to set appropriate coverage guidelines that we expect will reduce opioid risks among our members and, ultimately, the community.

Regarding the step therapy criteria, the patient selection criteria presented in this policy takes into consideration multiple factors, including drug allergies, renal insufficiency, and clinical evidence or patient history that suggests the generically available products will be ineffective or cause an adverse reaction to the patient. Based on a review of the data, in the absence of the above-mentioned caveats, there is no advantage of using a brand name oral long acting opioid over the available generic oral long acting opioids. Generic drugs are considered to have equal bioavailability and efficacy in comparison to brand name drugs.

References

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Policy History

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02/02/2012 Medical Policy Committee review

02/15/2012 Medical Policy Implementation Committee approval. Nucynta ER added to the policy. “Patient has tried and failed generic morphine sulfate extended-release capsules or generic oxycodone extended-release tablets” added to the patient selection criteria. “There is clinical evidence or patient history that suggests the generically available products will be ineffective or cause an adverse reaction to the patient” was added to the criteria of the policy.

02/07/2013 Medical Policy Committee review

02/20/2013 Medical Policy Implementation Committee approval. Changed “the following to including, but not limited to” in the eligible for coverage statement and added “name” to the not medically necessary statement for clarification. Coverage eligibility unchanged.

05/01/2014 Medical Policy Committee review

05/21/2014 Medical Policy Implementation Committee approval. Added Zohydro to the step therapy policy.



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05/07/2015 Medical Policy Committee review

05/20/2015 Medical Policy Implementation Committee approval. Added Hysingla ER to the policy.

06/02/2016 Medical Policy Committee review

06/20/2016 Medical Policy Implementation Committee approval. Added new products: Xtampza ER and branded oxycodone extended release. Added to step 1: hydromorphone extended release tablets. Removed the opt out for pregnancy. Added an opt out for patients aged 11-18.

06/01/2017 Medical Policy Committee review

06/21/2017 Medical Policy Implementation Committee approval. Added a new product (Arymo ER) to step 2.

10/05/2017 Medical Policy Committee review

10/18/2017 Medical Policy Implementation Committee approval. Title changed from “Long Acting Oral Opioids” to “Opioid Management/Long Acting Oral Opioid Step Therapy”. Hysingla ER and Oxycontin was removed from step therapy. The opioid management portion is divided into long acting and short acting. For short acting, the rejects will only trigger if the days’ supply is greater than 7 days or cumulative 21 days in a rolling 60 day period. If the drug is written for cancer pain or end of life care, it is eligible for coverage. If for neither of those, then there must be an agreement between the provider and patient regarding abuse, etc., a treatment plan, and an addiction risk assessment should have been performed. For long acting, there is no regard to days’ supply. All long acting Rx’s are subject to the policy. The same criteria apply (oncology pain or end of life care will be eligible for coverage), but in addition to the treatment plan, provider and patient agreement, and the addiction risk assessment, the member needs to have used a short acting opioid within the past 60 days and require around the clock pain control. Also for long acting products, preferred products need to be used prior to non-preferred products.

07/05/2018 Medical Policy Committee review

07/11/2018 Medical Policy Implementation Committee approval. Removed Avinza (removed from the market). Removed requirement for using a short acting opioid prior to a long acting opioid. Changed the prerequisite medication for buprenorphine patch and Belbuca.

11/08/2018 Medical Policy Committee review

11/21/2018 Medical Policy Implementation Committee approval. Added a new product, RoxyBond, to the short acting opioids PA section.

12/05/2019 Medical Policy Committee review

12/11/2019 Medical Policy Implementation Committee approval. Changed Belbuca to a preferred product. Changed branded Butrans Patch (5 mcg, 10 mcg, 15 mcg, 20 mcg) to a non-preferred agent, since these are now generic.



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10/01/2020 Medical Policy Committee review
10/07/2020 Medical Policy Implementation Committee approval. Added PA to levorphanol 2 mg and 3 mg tablets. Reflected that Butrans Patch 7.5 mcg is now available in generic form. Added a new generic, hydrocodone bitartrate, to the long acting PA section.
12/02/2021 Medical Policy Committee review
12/08/2021 Medical Policy Implementation Committee approval. Moved Hysingla ER to the list of long acting opioids in the PA section that requires a trial and failure of two products since it now has a generic equivalent. Added the generic equivalent of Hysingla ER to the list of long acting opioids that can be tried and failed prior to non-preferred long acting opioids in the PA section.
12/01/2022 Medical Policy Committee review
12/14/2022 Medical Policy Implementation Committee approval. No change to coverage.
12/07/2023 Medical Policy Committee review
12/13/2023 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/05/2024 Medical Policy Committee review
12/11/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 12/2025

****Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

