

PRIOR AUTHORIZATION POLICY

POLICY: Opioids – Long-Acting Products Prior Authorization Policy

Note: This is not an inclusive list. As new products become available, they will roll into this policy and the list will be updated periodically.

- Buprenorphine (i.e., Belbuca[®] buccal film, Butrans[®] transdermal patch)
- Fentanyl transdermal patch (Duragesic[®], generic)
- Hydrocodone extended-release capsules/tablets (e.g., Hysingla[™] ER, Zohydro[®] ER)
- Hydromorphone extended-release tablets (e.g., generic to discontinued Exalgo[®])
- Methadone dispersible tablets/oral solution/tablets (e.g., Diskets[®], Dolophine[®], Methadose[™], generic)
- Morphine sulfate extended-release capsules/tablets (e.g., Arymo[®] ER, Kadian[®], MS Contin[®], generic)
- Oxycodone extended-release capsules/tablets (e.g., Xtampza[®] ER, OxyContin[®])
- Oxymorphone extended-release tablets (e.g., generic [generic is not AB-rated to the discontinued Opana[®] ER formulation])
- Tapentadol extended-release tablets (e.g., Nucynta[®] ER)
- Tramadol extended-release capsules/tablets (e.g., Conzip[®], Ultram[®] ER, generic)

REVIEW DATE: 02/01/2023

OVERVIEW

All of the long-acting (LA) opioids are indicated for the **management of pain severe enough to require daily, around-the-clock, long-term opioid treatment** and for which alternative treatment options are inadequate.¹⁻¹⁶ OxyContin is the only product specifically indicated in pediatric patients 11 years to 18 years of age.⁶ Nucynta ER is the only product also indicated for the management of neuropathic pain associated with diabetic peripheral neuropathy in adults.¹ Methadone has additional indications for the treatment and maintenance treatment of opioid addiction (i.e., heroin or other morphine-like drugs).¹⁶ Note that methadone products, when used for the treatment of opioid addiction in detoxification or maintenance programs, shall be dispensed only by opioid treatment programs (and agencies, practitioners, or institutions by formal agreement with the program sponsor) certified by the Substance Abuse and Mental Health Services Administration and approved by the designated state authority.

The currently available LA opioids are buprenorphine, fentanyl, hydrocodone, hydromorphone, methadone, morphine sulfate, oxycodone, oxymorphone, tapentadol, and tramadol.¹⁻¹⁶

Guidelines

In 2022, the **Centers for Disease Control and Prevention (CDC)** published an updated guideline for prescribing opioids for pain.¹⁷ Nonopioid therapies are at least as effective as opioids for many common types of acute pain, and nonopioid therapies are preferred for subacute and chronic pain. Clinicians should maximize the use of nonpharmacologic and nonopioid pharmacologic therapies as appropriate for the specific condition and patient and only consider initiating opioid therapy if expected benefits for pain and function are anticipated to outweigh risks to the patient. Multiple noninvasive nonpharmacologic interventions (e.g., aerobic, aquatic, or resistance exercises, weight loss, psychological therapy, spinal manipulation, low-level laser therapy, massage, mindfulness-based stress reduction, yoga, tai chi, qigong, acupuncture, cognitive behavioral therapy, and spinal manipulation) are associated with improvements in pain, function, or both, that are sustained after treatment and are not associated with serious harms. Non-opioid drugs (e.g., tricyclic antidepressants, serotonin and norepinephrine reuptake inhibitor [SNRI])

antidepressants, duloxetine, selected antiseizure medications (e.g., pregabalin, gabapentin, oxcarbazepine), capsaicin and lidocaine patches, and nonsteroidal anti-inflammatory drugs [NSAIDs]) are associated with small to moderate improvements in chronic pain and function for certain chronic pain conditions.

Before initiating opioid therapy for patients with pain, clinicians should discuss with patients the realistic benefits and known risks of opioid therapy.¹⁷ Before starting ongoing opioid therapy for patients with subacute or chronic pain, clinicians should work with patients to establish treatment goals for pain and function and consider how opioid therapy will be discontinued if benefits do not outweigh risks. When opioids are initiated, clinicians should prescribe the lowest effective dosage of immediate-release opioids for no longer than needed for the expected duration of pain severe enough to require opioids. During ongoing opioid therapy, clinicians should collaborate with patients to evaluate and carefully weigh the benefits and risks of continuing opioid therapy and exercise care when increasing, continuing, or reducing opioid dosage. The guideline recommends that clinicians should not initiate opioid treatment with LA opioids for patients who are opioid-naïve and should not prescribe LA opioids for intermittent use. LA opioids should be reserved for severe, continuous pain. Before starting and periodically during continuation of opioid therapy, clinicians should evaluate the risk for opioid-related harms and should work with patients to incorporate relevant strategies to mitigate risk, including offering naloxone and reviewing potential interactions with any other prescribed medications or substances used. When prescribing initial opioid therapy and periodically during opioid therapy, clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or combinations that put the patient at high risk for overdose. When prescribing opioids for subacute or chronic pain, clinicians should consider the benefits and risks of toxicology testing to assess for prescribed medications as well as other prescribed and nonprescribed controlled substances.

The 2020 **American Society of Hematology** guideline for the management of acute and chronic pain in patients with sickle cell disease states that pain causes significant morbidity for those living with sickle cell disease and manifests as acute intermittent pain, chronic daily pain, and acute-on-chronic pain.¹⁸ For adults and children with chronic pain who are receiving chronic opioid therapy, are functioning well, and have perceived benefit, the guideline suggests shared decision making for continuation of chronic opioid therapy. For adults and children with chronic pain who are receiving chronic opioid therapy, are functioning poorly, or are at high risk for aberrant opioid use or toxicity, the guideline suggests against continuation of chronic opioid therapy.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of long-acting opioids. Long-acting opioids are controlled substances (CII with the exception of tramadol-containing products which are CIV) which can be misused and abused. Because of the specialized skills required for evaluation and diagnosis of patients with sickle cell disease as well as the monitoring required for adverse events and long-term efficacy, approval requires LA opioids to be prescribed by or in consultation with a hematologist for patients with this diagnosis. All approvals are provided for the duration noted below.

Note: This policy includes long-acting formulations of the medications listed on page 1; the list is not inclusive. As new products become available, they will roll into this policy and the list will be updated periodically.

Automation: A patient with a history of a long-acting opioid within the 130-day look-back period is excluded from Prior Authorization. If the patient has a prescription for a cancer medication (see Appendix A) within a 180-day period, the claim will adjudicate. When available, the ICD-10 codes for cancer will be used as part of automation to allow approval of the requested medication (see Appendix B).

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of long-acting opioids is recommended in those who meet the following criteria:

- I. Coverage of all long-acting opioids, except fentanyl transdermal products, is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. Pain Severe Enough to Require Daily, Around-the-Clock, Long-Term Opioid Treatment.

Approve for 1 year if the patient meets ONE of the following criteria (A, B, C, or D):

- A) Patient has a cancer diagnosis; OR
- B) Patient is in a hospice program, end-of-life care, or palliative care; OR
- C) Patient meets BOTH of the following criteria (i and ii):
 - i) Patient has diagnosis of sickle cell disease; AND
 - ii) Medication is prescribed by or in consultation with a hematologist; OR
- D) Patient meets ALL of the following criteria (i, ii, iii, iv, v, vi, and vii):
 - i. Patient is not opioid-naïve; AND
 - ii. Non-opioid therapies have been optimized and are being used in conjunction with opioid therapy, according to the prescriber; AND
Note: Examples of non-opioid therapies include non-opioid medications (e.g., nonsteroidal anti-inflammatory drugs, tricyclic antidepressants, serotonin and norepinephrine reuptake inhibitors, antiseizure medications), physical therapy, exercise therapy, weight loss, and cognitive behavioral therapy.
 - iii. Patient's of controlled substance prescriptions has been checked using the state prescription drug monitoring program (PDMP), according to the prescriber; AND
 - iv. Risks (e.g., addiction, overdose) and realistic benefits of opioid therapy have been discussed with the patient, according to the prescriber; AND
 - v. Treatment plan (including goals for pain and function) is in place and reassessments (including pain levels and function) are scheduled at regular intervals, according to the prescriber.
 - vi. Need for a naloxone prescription has been assessed and naloxone has been ordered, if necessary, according to the prescriber; AND
 - vii. Need for periodic toxicology testing has been assessed and ordered, if necessary, according to the prescriber.

2. Opioid Addiction (Dependence) [methadone products only]. Approve methadone for 1 year if the patient meets ONE of the following criteria (A or B):

- A) Methadone is dispensed by an opioid treatment program certified by the Substance Abuse and Mental Health Services Administration and approved by the designated state authority; OR
- B) Methadone is being prescribed during an emergency period of ≤ 3 days while definitive care for the addiction is being sought in an appropriately licensed facility.

- II. Coverage of fentanyl transdermal products is recommended in those who meet the following criteria:

FDA-Approved Indication

1. Pain Severe Enough to Require Daily, Around-the-Clock, Long-Term Opioid Treatment.

Approve for 1 year if the patient has a cancer diagnosis.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of long-acting opioids is not recommended in the following situations:

1. **Acute Pain.** According to the CDC guideline for prescribing opioids for chronic pain, clinicians should not prescribe extended-release/long-acting opioids for the treatment of acute pain due to the longer half-lives and longer duration of effects (e.g., respiratory depression) with extended-release/long-acting opioids.¹⁷
2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Nucynta® ER extended-release oral tablets [prescribing information]. Stoughton, MA: Collegium; March 2021.
2. Embeda® extended-release capsules [prescribing information]. New York, NY: Pfizer; October 2019.
3. Kadian® capsules [prescribing information]. Madison, NJ: Allergan; March 2021.
4. Avinza® capsules [prescribing information]. New York, NY: Pfizer; May 2014.
5. MS Contin® tablets [prescribing information]. Stamford, CT: Purdue; March 2021.
6. OxyContin® tablets [prescribing information]. Stamford, CT: Purdue; October 2021.
7. Oxymorphone ER tablets [prescribing information]. Bridgewater, NJ: Amneal; June 2022.
8. Exalgo® extended-release tablets [prescribing information]. Webster Groves, MO: SpecGx; October 2019.
9. Zohydro® ER extended-release capsules [prescribing information]. Morristown, NJ: Currax; March 2021.
10. Hysingla™ ER extended-release tablets [prescribing information]. Stamford, CT: Purdue; March 2021.
11. Xtampza ER® extended-release capsules [prescribing information]. Cincinnati, OH: Patheon; March 2021.
12. Arymo® ER extended-release tablets [prescribing information]. Wayne, PA: Egalet; October 2019.
13. Conzip® extended-release capsules [prescribing information]. Bridgewater, NJ: Vertical; September 2021.
14. Belbuca® buccal film [prescribing information]. Raleigh, NC: BioDelivery Sciences; June 2022.
15. Duragesic® transdermal system [prescribing information]. Titusville, NJ: Janssen; March 2021.
16. Dolophine® [prescribing information]. Eatontown, NJ: West-Ward; June 2021.
17. Dowell D, Ragan KR, Jones CM, et al. CDC Clinical Practice Guideline for Prescribing Opioids for Pain - United States, 2022. *MMWR Recomm Rep.* 2022;71(3):1-95.
18. Brandow AM, Carroll CP, Creary S, et al. American Society of Hematology 2020 guidelines for sickle cell disease: management of acute and chronic pain. *Blood Adv.* 2020;4(12):2656-2701.

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	05/18/2022
Early Annual Revision	Pain Severe Enough to Require Daily, Around-the-Clock, Long-Term Opioid Treatment: Added new approval diagnosis of sickle cell disease and requirement that it is prescribed by or in consultation with a hematologist. Added criterion that the need for a naloxone prescription has been assessed and naloxone has been ordered, if necessary, according to the prescriber. Added criterion that the need for periodic toxicology testing has been assessed and ordered, if necessary, according to the prescriber.	02/01/2023

APPENDIX A

Note: This list is not inclusive. As new STCs become available, they will roll into this policy and the list will be updated periodically.

STC*	STC Description
0470	ANTINEOPLASTIC - ALKYLATING AGENTS
0471	ANTINEOPLASTIC - ANTIMETABOLITES
0472	ANTINEOPLASTIC - VINCA ALKALOIDS
0473	ANTIBIOTIC ANTINEOPLASTICS
0475	ANTINEOPLASTICS, MISCELLANEOUS
6323	ANTINEOPLASTIC - ANTIANDROGENIC AGENTS
7235	ANTINEOPLASTICS ANTIBODY/ANTIBODY-DRUG COMPLEXES
7977	ANTINEOPLASTIC IMMUNOMODULATOR AGENTS
8254	ANTINEOPLASTIC LHRH(GNRH) AGONIST, PITUITARY SUPPR.
8460	ANTINEOPLASTIC LHRH(GNRH) ANTAGONIST,PITUIT.SUPPRS
8569	ANTINEOPLASTIC EGF RECEPTOR BLOCKER MCLON ANTIBODY
8585	ANTINEOPLAST HUM VEGF INHIBITOR RECOMB MC ANTIBODY
9150	ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS
B759	ANTINEOPLAST, HISTONE DEACETYLASE (HDAC) INHIBITORS
C232	ANTINEOPLASTIC - MTOR KINASE INHIBITORS
C370	ANTINEOPLASTIC - EPOTHILONES AND ANALOGS
C532	ANTINEOPLASTIC - TOPOISOMERASE I INHIBITORS
C593	ANTINEOPLASTIC - AROMATASE INHIBITORS
D426	ANTINEOPLASTIC - IMMUNOTHERAPY, THERAPEUTIC VAC
D560	ANTINEOPLASTIC - HALICHONDRIN B ANALOGS
D687	CYTOTOXIC T-LYMPHOCYTE ANTIGEN (CTLA-4) RMC ANTIBODY
E039	ANTINEOPLASTIC - JANUS KINASE (JAK) INHIBITORS
E150	ANTINEOPLASTIC - HEDGEHOG PATHWAY INHIBITOR
E600	ANTINEOPLASTIC - VEGF-A,B AND PLGF INHIBITORS
F495	ANTINEOPLASTIC - INTERLEUKIN-6(IL-6)INHIB,ANTIBODY
F501	ANTINEOPLASTIC - VEGFR ANTAGONIST
F665	ANTINEOPLASTIC, ANTI-PROGRAMMED DEATH-1 (PD-1) MAB
G545	ANTINEOPLASTIC - IMMUNOTHERAPY, VIRUS-BASED AGENTS
G575	ANTINEOPLASTIC - MEK1 AND MEK2 KINASE INHIBITORS
G590	ANTINEOPLASTIC - ANTI-CD38 MONOCLONAL ANTIBODY
G607	ANTINEOPLASTIC - ANTI-SLAMF7 MONOCLONAL ANTIBODY
G802	ANTINEOPLASTIC- B CELL LYMPHOMA-2(BCL-2) INHIBITORS
G857	ANTI-PROGRAMMED CELL DEATH-LIGAND 1 (PD-L1) MAB
H018	ANTINEOPLASTIC, PDGFR-ALPHA BLOCKER MC ANTIBODY
H214	ANTINEOPLASTIC COMB-KINASE AND AROMATASE INHIBIT
H289	ANTINEOPLASTIC-ISOCITRATE DEHYDROGENASE INHIBITORS
H309	ANTINEOPLASTIC – ANTIBIOTIC AND ANTIMETABOLITE
H317	ANTINEOPLASTIC – CD22 ANTIBODY-CYTOTOXIC ANTIBIOTIC
H324	ANTINEOPLASTIC- CD19 DIR. CAR-T CELL IMMUNOTHERAPY
H329	ANTINEOPLASTIC – CD33 ANTIBODY-CYTOTOXIC ANTIBIOTIC
H617	ANTINEOPLASTIC – BRAF KINASE INHIBITORS
H768	ANTINEOPLASTIC-CD22 DIRECT ANTIBODY/CYTOTOXIN CONJ
H868	ANTINEOPLASTIC-CD123-DIRECTED CYTOTOXIN CONJUGATE
I054	ANTINEOPLASTIC-SELECT INHIB OF NUCLEAR EXP (SINE)
I264	ANTINEOPLASTIC – PROTEIN METHYLTRANSFERASE INHIBITORS
I482	ANTINEOPLASTIC – CD19 (B LYMPHOCYTE) MC ANTIBODY

* Excluding topical products.

APPENDIX B

*Indicates the inclusion of subheadings.