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®, Butrans®)
- Fentanyl transdermal (Duragesic®, generic)
- Hydrocodone extended-release (e.g., Hysingla™ ER, Zohydro® ER)
- Hydromorphone extended-release (e.g., Exalgo® [brand discontinued 2019], generic)
- Methadone (e.g., Diskets®, Dolophine®, Methadose™, generic)
- Morphine sulfate extended-release (e.g., Arymo® ER, Embeda® [brand discontinued 2019], Kadian®, MS Contin®, generic)
- Oxycodone extended-release (e.g., Xtampza® ER, OxyContin®)
- Oxymorphone extended-release (e.g., generic [generic is not AB-rated to the discontinued Opana® ER formulation])
- Tapentadol extended-release (e.g., Nucynta® ER)
- Tramadol extended-release (e.g., Conzip®, Ultram® ER, generic)

REVIEW DATE: 05/12/2021

OVERVIEW

All of the long-acting 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 long-acting (due to either an extended-release formulation or a long half-life [i.e., methadone]) opioids are buprenorphine, fentanyl, hydrocodone, hydromorphone, methadone, morphine sulfate, oxycodone, oxymorphone, tapentadol, and tramadol.[1-16]

Guidelines

In 2016, the Centers for Disease Control (CDC) published a guideline for prescribing opioids for chronic pain.[17,18] The guideline provides recommendations for primary care providers who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care. In the guideline, chronic pain is defined as pain that typically lasts greater than 3 months or past the time of normal tissue healing, resulting from an underlying medical disease or condition, injury, medical treatment, inflammation, or an unknown cause. To support the guideline an updated review of long-term opioid therapy for chronic pain outside of end-of-life care was undertaken and the results revealed that evidence remains limited, with insufficient evidence to determine long-term benefits of chronic opioid therapy versus no opioid therapy. However, the evidence did suggest a risk for serious harms with long-term opioid therapy that appears to be dose-dependent.

The CDC guideline recommendations are grouped into three areas: when to initiate or continue opioids for chronic pain; opioid selection, dosage, duration, follow-up, and discontinuation; and assessing risk and addressing harms of opioid use.[17] Nonpharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain; if opioids are used, they should be combined with nonpharmacologic therapy and non-opioid pharmacologic therapy, as appropriate. Before starting and periodically during opioid therapy, healthcare providers should discuss with their patient the risks and realistic benefits of opioid therapy and also the shared responsibilities for managing therapy. When starting opioid therapy for chronic pain, immediate-release opioids should be prescribed at the lowest effective dosage instead of initiating therapy with extended-release/long-acting opioids. Carefully reassess individual benefits and risks when increasing opioid dosages to ≥ 50 morphine milligram equivalents (MME)/day and avoid increasing dosage to ≥ 90 MME/day whenever possible. Healthcare providers should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy or of dose escalation and evaluate continued therapy with patients at least every 3 months. If benefits do not outweigh harms of continued opioid therapy, other therapies should be optimized and opioid doses tapered to lower dosages and/or discontinued. Before starting and periodically during continuation of opioid therapy, healthcare providers should evaluate risk factors for opioid-related harms and incorporate strategies into the management plan to mitigate risk, including offering naloxone. The patient's history of controlled substance prescriptions should be periodically reviewed using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations putting them at high risk for overdose. Urine drug testing is recommended before starting opioid therapy and at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs; treatment should be offered to and/or arranged for patients with opioid use disorder.

The CDC guideline states that long-term opioid use often begins with treatment of acute pain.[17] When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids (i.e., ≤ 3 days and only rarely > 7 days).

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. 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. All approvals are provided for the duration noted below.

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 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 or C):
   - **A)** Patient has a cancer diagnosis; OR
   - **B)** Patient is in a hospice program, end-of-life care, or palliative care; OR
   - **C)** Patient has chronic pain but does not have a cancer diagnosis. Approve for 1 year if the patient meets ALL of the following criteria (i, ii, iii, iv, and v):
     - **i.** Patient is not opioid naïve; AND
     - **ii.** Non-opioid therapies (e.g., non-opioid medications [e.g., nonsteroidal anti-inflammatory drugs {NSAIDs}, tricyclic antidepressants, serotonin and norepinephrine reuptake inhibitors {SNRIs}, anticonvulsants], exercise therapy, weight loss, cognitive behavioral therapy) have been optimized and are being used in conjunction with opioid therapy according to the prescribing physician; AND
     - **iii.** Patient's history of controlled substance prescriptions has been checked using the state prescription drug monitoring program (PDMP), unless unavailable in the state (see note below), according to the prescribing physician; AND
       Note: As of 05/12/2021, the state of Missouri is the only state in the US that does not have a statewide PDMP program in place.
     - **iv.** Risks (e.g., addiction, overdose) and realistic benefits of opioid therapy have been discussed with the patient according to the prescribing physician; 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 prescribing physician.

2. **Opioid Addiction (Dependence)** [methadone products only]. Approve methadone for 1 year if ONE of the following criteria (A or B) is met:
   - **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 Indications

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.[1]

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 Pharmaceutical; 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 Pharma.; March 2021.
6. OxyContin® tablets [prescribing information]. Stamford, CT: Purdue Pharma; March 2021.
7. Oxymorphone ER tablets [prescribing information]. Bridgewater, NJ: Amneal Pharmaceuticals; March 2021.
8. Exalgo® extended-release tablets [prescribing information]. Webster Groves, MO: SpecGx; October 2019.
9. Zohydro® ER extended-release capsules [prescribing information]. Morristown, NJ: Currax Pharmaceuticals; March 2021.
10. Hysingla™ ER extended-release tablets [prescribing information]. Stamford, CT: Purdue Pharma; March 2021.
11. Xtampza ER® extended-release capsules [prescribing information]. Cincinnati, OH: Patheon Pharmaceuticals; 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 Pharmaceuticals; March 2021.
14. Belbuca® buccal film [prescribing information]. Raleigh, NC: BioDelivery Sciences; March 2021.
15. Duragesic® transdermal system [prescribing information]. Titusville, NJ: Janssen; March 2021.
16. Dolophine® [prescribing information]. Eatontown, NJ: West-Ward; October 2019.
17. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. *MMWR Recommendations and Reports*. 2016;65(1):1-49.
18. Centers for Disease Control and Prevention. Checklist for prescribing opioids for chronic pain. Available at: https://www.cdc.gov/drugoverdose/pdf/pdo_checklist-a.pdf. Accessed on May 10, 2021.

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

* Excluding topical products

APPENDIX B

ICD-10 Codes
Cancer-related codes
C00.* to D09.*
D3A.* to D48.*
E34.0*
Q85.0*

*Indicates the inclusion of subheadings.