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® [brand discontinued], generic)
- Hydrocodone extended-release capsules/tablets (e.g., Hysingla® ER, Zohydro® ER [brand discontinued])
- Hydromorphone extended-release tablets (e.g., generic to discontinued Exalgo®)
- Morphine sulfate extended-release capsules/tablets (e.g., Arymo® ER [brand discontinued], Kadian® [brand discontinued], 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 [brand discontinued], generic)

REVIEW DATE: 01/17/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

All of the long-acting (LA) opioids are indicated for the **management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic** and for which alternative treatment options are inadequate.[1-9] OxyContin is the only product specifically indicated in pediatric patients 11 years to 18 years of age.[3] Nucynta ER is the only product also indicated for the management of neuropathic pain associated with diabetic peripheral neuropathy in adults.[1]

The currently available LA opioids are buprenorphine, fentanyl, hydrocodone, hydromorphone, morphine sulfate, oxycodone, oxymorphone, tapentadol, and tramadol.[1-9]

Guidelines

In 2022, the **Centers for Disease Control and Prevention (CDC)** published an updated guideline for prescribing opioids for pain.[10] 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.[10] 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.[11] 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 buprenorphine products which are CIII and 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.

- **Buprenorphine (i.e., Belbuca® buccal film, Butrans® transdermal patch)**
- **Fentanyl transdermal patch (Duragesic® [brand discontinued], generic)**
- **Hydrocodone extended-release capsules/tablets (e.g., Hysingla® ER, Zohydro® ER [brand discontinued])**
- **Hydromorphone extended-release tablets (e.g., generic to discontinued Exalgo®)**
- **Morphine sulfate extended-release capsules/tablets (e.g., Arymo® ER [brand discontinued], Kadian® [brand discontinued], 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 [brand discontinued], generic)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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 (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 (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 (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 history 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.

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 COVERED

- **Buprenorphine (i.e., Belbuca® buccal film, Butrans® transdermal patch)**
- **Fentanyl transdermal patch (Duragesic® [brand discontinued], generic)**
- **Hydrocodone extended-release capsules/tablets (e.g., Hysingla® ER, Zohydro® ER [brand discontinued])**
- **Hydromorphone extended-release tablets (e.g., generic to discontinued Exalgo®)**
- **Morphine sulfate extended-release capsules/tablets (e.g., Arymo® ER [brand discontinued], Kadian® [brand discontinued], 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 [brand discontinued], generic)**

is(are) considered experimental, investigational, or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

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; December 2023.
2. MS Contin® tablets [prescribing information]. Stamford, CT: Purdue; December 2023.
3. OxyContin® tablets [prescribing information]. Stamford, CT: Purdue; December 2023.
4. Oxymorphone ER tablets [prescribing information]. Bridgewater, NJ: Amneal; December 2023.
5. Hysingla® ER extended-release tablets [prescribing information]. Stamford, CT: Purdue; December 2023.
6. Xtampza ER® extended-release capsules [prescribing information]. Cincinnati, OH: Patheon; December 2023.

7. Conzip® extended-release capsules [prescribing information]. Alpharetta, GA: Vertical; December 2023.
8. Belbuca® buccal film [prescribing information]. Raleigh, NC: BioDelivery Sciences; December 2023.
9. Fentanyl transdermal system [prescribing information]. Morgantown, WV: Mylan; December 2023.
10. 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.
11. 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.

HISTORY

Type of Revision	Summary of Changes	Review Date
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
Early Annual Revision	**Methadone:** Methadone products were removed from the policy. Methadone will be moved to a separate Methadone PA policy. **Opioid Addiction (Dependence)** [methadone products only]: Criteria removed from the Opioids – Long-Acting Products PA policy and moved to Opioids -– Methadone PA policy.	01/17/2024

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

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

*Indicates the inclusion of subheadings.