Cigna National Formulary Coverage Policy

Effective Date..... 3/1/2023
Next Review Date..... 3/1/2024

Drug Quantity Management – Per RX
Opioids – Short-Acting Products (Pediatrics)

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Product Identifier(s)

74974, 67866

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. 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.

National Formulary Medical Necessity

Drugs Affected
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.

- Alfentanil – injectable
- Benzhydrocodone – combination oral tablets
- Buprenorphine – injectable
- Butorphanol – injectable, nasal solution
- Codeine – oral tablets, combination product oral tablets/capsules, combination product oral solution, combination product oral suspension
- Dihydrocodeine – combination oral tablets/capsules
- Fentanyl – transmucosal lozenges, buccal tablets, nasal solution, sublingual spray, sublingual tablet, injectable, transdermal patches
- Hydrocodone – combination product oral tablets, combination product oral solution
- Hydromorphone – injectable, oral tablets, oral solution, rectal suppositories
- Levorphanol – oral tablets
- Meperidine – oral tablets, oral solution, injectable

- Morphine – oral tablets, oral solution, injectable, rectal suppositories
- Nalbuphine – injectable
- Opium/Belladonna – rectal suppositories
- Oxycodone – oral tablets, oral capsules, oral solution, combination product oral tablets, combination product oral solution
- Oxymorphone – oral tablets, injectable
- Pentazocine – injectable
- Pentazocine/naloxone – oral tablets
- Remifentanil – injectable
- Sufentanil – injectable
- Tapentadol – oral tablets
- Tramadol – oral tablets, combination product oral tablets

This Drug Quantity Management program has been developed to restrict the initial days' supply of short-acting opioids for pediatric individuals (< 18 years of age) to 3 days, thus decreasing the quantity dispensed to align with current guidelines and prevent stockpiling and/or misuse. If the Drug Quantity Management rule is not met for the requested product at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Note: This policy includes multiple 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. Point of sale alerts also manage the quantity of opioid product distribution. Those point of sale alerts occur prior to any Utilization Management edits.

Criteria

Cigna covers quantities as medically necessary when the following criteria are met:

1. Approve the requested quantity if the individual meets one of the following criteria (A, B, C, or D):
- **A)** Individual has a cancer diagnosis; OR
- **B)** Individual is in hospice program, end-of-life care, or palliative care; OR
- **C)** Individual meets BOTH of the following criteria (i and ii):
  - **i.** Individual has a diagnosis of sickle cell disease; AND
  - **ii.** Medication is being prescribed by or in consultation with a hematologist; OR
- **D)** Individual meets ALL of the following criteria (i, ii, iii, iv, and v):
  - **i.** Non-opioid therapies (e.g., nonsteroidal anti-inflammatory drugs [NSAIDs], acetaminophen) have provided an inadequate response or are inappropriate according to the prescriber; AND
  - **ii.** Individual's history of controlled substance prescriptions has been checked using the state prescription drug monitoring program (PDMP), according to the prescribing physician; AND
  - **iii.** Risks (e.g., addiction, overdose) and realistic benefits of opioid therapy have been discussed with the individual according to the prescriber; AND
  - **iv.** Need for a naloxone prescription has been assessed and naloxone has been ordered, if necessary, according to the prescriber; AND
  - **v.** Need for periodic scheduled toxicology testing has been assessed and ordered, if necessary, according to the prescriber.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

Overview
Short-acting opioids are indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.[1]

Guidelines
In 2022, the **Centers for Disease Control and Prevention (CDC)** published an updated guideline for prescribing opioids for pain.[1] 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.[1] 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.

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.[1] 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.[2] 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.

References

1. 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.
2. 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.

Revision History

Type of Revision	Summary of Changes	Approval Date
Early Annual Revision	A note was added to state "Point of sale alerts also manage the quantity of opioid product distribution. Those point of sale alerts occur prior to any Advanced Utilization Management (AUM) edits." New override criteria were added to approve the quantity requested if the patient has a diagnosis of sickle cell disease and the medication 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.

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

SK_STC	SK_STC_Desc*
7235	ANTINEOPLASTICS ANTIBODY/ANTIBODY-DRUG COMPLEXES
0475	ANTINEOPLASTICS,MISCELLANEOUS
I054	ANTINEOPLASTIC-SELECT INHIB OF NUCLEAR EXP (SINE)
G857	ANTI-PROGRAMMED CELL DEATH-LIGAND 1 (PD-L1) MAB
D687	CYTOTOXIC T-LYMPHOCYTE ANTIGEN(CTLA-4)RMC ANTIBODY
I738	ANTINEOPLASTIC – EGFR AND MET RECEPTOR INHIB, MAB
I746	ANTINEOPLASTIC – KRAS INHIBITOR
I832	ANTINEOPLASTIC – HYPOXIA INDUCIBLE FACTOR (HIF) INH
I938	ANTINEOPLASTIC – IMMUNOTHERAPY, T-CELL ENGAGER
I996	ANTINEOPLASTIC – IMMUNOTHERAPY CHECKPOINT INHIB COMB

* Excluding topical products

Appendix B

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

*Indicates the inclusion of subheadings.