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

Drug Quantity Management – Per Days
Opioids – Morphine Milligram Equivalent (200)

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Product Identifier(s)

59582

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.

- Benzhydrocodone combination oral tablets
- Butorphanol injectable, nasal solution
- Codeine oral tablets, combination product oral tablets/capsules, combination product oral solution
- Dihydrocodeine combination oral tablets/capsules
- Fentanyl transmucosal lozenges, buccal tablets, nasal solution, sublingual spray, sublingual tablet, injectable, transdermal patches
- Hydrocodone oral tablets, oral capsules, 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
- Methadone oral tablets, oral solution, injectable
- Morphine oral capsules, oral tablets, oral solution,injectable, rectal suppositories

- Nalbuphine injectable
- Oxycodone oral tablets, oral capsules, oral solution, combination product oral tablets, combination product oral solution
- Oxymorphone oral tablets
- Pentazocine/naloxone oral tablets
- Tapentadol oral tablets
- Tramadol oral capsules, oral tablets, oral solution, combination product oral tablets

This Drug Quantity Management program has been developed to prevent stockpiling, misuse and/or overuse of opioids.

The MME (200) DQM policy works in combination with the MME (90) DQM policy. A total quantity of opioid of up to MME of 200 per day is approved if the individual meets the criteria in the MME 90 policy.

A MME is calculated for each individual's opioid prescription claim using the appropriate conversion factor associated with the opioid product for the claim. After converting the individual's opioid medications to their MME, the individual's cumulative prescription opioid daily dose (the MME per day) is calculated to determine if the member exceeded the 200 MME threshold. If a prescription will cause the individual to exceed the cumulative daily MME threshold of 200, then it will reject and additional coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration, unless otherwise noted.

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. Opioid cough and cold products are excluded from the calculations of MMEs. Point of sale alerts also manage the quantity of opioid product distribution. Those point of sale alerts occur prior to any Utilization Management edits.

Documentation: Documentation is required for approval of additional quantities of opioids over 600 MMEs per day as noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts, and/or other information.

Criteria

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

Requests for a daily morphine milligram equivalent dose of > 200 and ≤ 600:

1. Approve the requested quantity not to exceed 600 morphine milligram equivalents (MME) daily for up to 1 year, 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, v, and vi):
  - **i.** 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), exercise therapy, physical therapy, weight loss, and cognitive behavioral therapy.
  - **ii.** Individual's history of controlled substance prescriptions has been checked using the state prescription drug monitoring program (PDMP), according to the prescriber; 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.** Individual has a treatment plan or pain contract (including goals for pain and function) in place and has reassessments (including pain levels and function) scheduled at regular intervals according to the prescriber; AND

v. Need for a naloxone prescription has been assessed and naloxone has been ordered, if necessary, according to the prescriber; AND

vi. Need for periodic toxicology testing has been assessed and ordered, if necessary, according to the prescriber.

Note: A morphine milligram equivalent calculator can be found at: https://www.mdcalc.com/calc/10170/morphine-milligram-equivalents-mme-calculator.

Requests for a daily morphine milligram equivalent dose of > 600:

1. Approve the morphine milligram equivalent (MME) daily dose requested for up to 1 year, 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):
     a. Individual has a diagnosis of sickle cell disease; AND
     b. Medication is being prescribed by or in consultation with a hematologist; OR
   - **D)** Individual meets ALL of the following criteria (i, ii, iii, iv, v, and vi):
     a. 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), exercise therapy, physical therapy, weight loss, and cognitive behavioral therapy.
     b. Individual's history of controlled substance prescriptions has been checked using the state prescription drug monitoring program (PDMP), according to the prescriber; AND
     c. Risks (e.g., addiction, overdose) and realistic benefits of opioid therapy have been discussed with the individual according to the prescriber; AND
     d. Individual has a treatment plan or pain contract (including goals for pain and function) in place and has reassessments (including pain levels and function) scheduled at regular intervals **[documentation required]**; AND
     e. Need for a naloxone prescription has been assessed and naloxone has been ordered, if necessary, according to the prescriber; AND
     f. Need for periodic toxicology testing has been assessed and ordered, if necessary, according to the prescriber.

Note: A morphine milligram equivalent (MME) calculator can be found at: https://www.mdcalc.com/calc/10170/morphine-milligram-equivalents-mme-calculator.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

Overview

Use of morphine milligram equivalents (MME) as a method to assess opioid-associated risk based on overall daily opioid dose has been cited in the professional literature and pain guidelines.[1] There is not one universally accepted MME per day that has been found to represent the dose at which a patient is at the greatest risk for adverse events (AEs). However, there is general consensus that as opioid doses are increased, the risk of AEs also increases. Additional guideline information is summarized below. Of note, the Centers for Medicare and Medicaid Services (CMS) require plan sponsors to implement a point-of-service safety edit at 90 MME and recommend a hard safety edit at a threshold of 200 MME.[2]

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. While they do not make specific dosing recommendations, it is noted that many patients do not experience additional pain reduction or improved function from increasing their opioid dose to ≥ 50 MME per day, but they are exposed to progressive increased risks. Therefore, before increasing a patient's dose to ≥ 50 MME per day, clinicians should pause and reassess the individual patient's benefits and risks. Guidelines also note that few trials have evaluated doses ≥ 90 MME per day.

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.[3] 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. Announcement of calendar year (CY) 2019 Medicare Advantage capitation rates and Medicare Advantage and Part D payment policies and final call letter. The Centers for Medicare and Medicaid Services. Available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf. Accessed January 26, 2023.
3. 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 Utilization Management edits." **Requests for a daily morphine milligram equivalent dose of > 200 and ≤ 600:** New override criteria were added to approve 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 periodic toxicology testing has been assessed and ordered, if necessary, according to the prescriber. **Requests for a daily morphine milligram equivalent dose of > 600:** New override criteria were added to approve 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 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 - MICROTUBULE INHIBITORS
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
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 - 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 INHIBIT
I482	ANTINEOPLASTIC - CD19 (B LYMPHOCYTE) MC ANTIBODY
I738	ANTINEOPLASTIC - EGFR AND MET RECEPTOR INHIB, MAB
I746	ANTINEOPLASTIC - KRAS PROTEIN 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

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

* Indicates the inclusion of subheadings.