Immediate Release Opioid Analgesics (Brand and Generic): Acute Pain Duration Limit with MME Limit and Post Limit Policy

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Codeine Sulfate

- Codeine sulfate tablets are indicated for the management of mild to moderate pain, where treatment with an opioid is appropriate and for which alternative treatments are inadequate.
- Limitations of Use
  - Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve codeine sulfate tablets for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or opioid combination products):
    - Have not been tolerated or are not expected to be tolerated.
    - Have not provided adequate analgesia or are not expected to provide adequate analgesia.

Dilaudid (hydromorphone hydrochloride)

Dilaudid (hydromorphone hydrochloride) Oral Solution and Dilaudid (hydromorphone hydrochloride) Tablets are indicated for the management of pain severe enough to require an opioid analgesic for which alternative treatments are inadequate.

- Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve Dilaudid (hydromorphone hydrochloride) Oral Solution and Dilaudid (hydromorphone hydrochloride) Tablets for use in patients for whom alternative treatment options [e.g., non-opioid analgesics or opioid combination products]:
  - Have not been tolerated, or are not expected to be tolerated,
  - Have not provided adequate analgesia, or are not expected to provide adequate analgesia

Hydromorphone Hydrochloride

Hydromorphone hydrochloride oral solution, suppositories, and tablets are indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

- Limitations of Use
  - Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve hydromorphone hydrochloride oral solution, suppositories, and tablets for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or opioid combination products):
    - Have not been tolerated or are not expected to be tolerated.
    - Have not provided adequate analgesia or are not expected to provide adequate analgesia.

Levorphanol Tartrate

Levorphanol Tartrate tablets are indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

- Limitations of Use
  - Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve levorphanol tartrate tablets for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or opioid combination products):
    - Have not been tolerated or are not expected to be tolerated.
    - Have not provided adequate analgesia or are not expected to provide adequate analgesia.

Meperidine Hydrochloride

- Oral Solution, Tablets
  - Meperidine hydrochloride oral solution and tablets are indicated for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.
- Limitations of Use
  - Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve meperidine hydrochloride oral solution and tablets for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or opioid combination products):
    - Have not been tolerated or are not expected to be tolerated.
    - Have not provided adequate analgesia or are not expected to provide adequate analgesia.

Meperidine hydrochloride oral solution and tablets should not be used for treatment of chronic pain. Prolonged meperidine use may increase the risk of toxicity (e.g., seizures) from the accumulation of the meperidine metabolite, normeperidine.

Morphine Sulfate

- Oral Solution
  - Morphine sulfate oral solution is indicated for the management of:
    - Adults with acute and chronic pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.
    - Pediatric patients 2 years of age and older with acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.
  - Morphine sulfate oral solution 20 mg/mL is indicated for the relief of acute and chronic pain in opioid-tolerant patients.
- Suppositories
  - Morphine sulfate suppositories are indicated for the management of acute and chronic pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

- Tablets
  - Adults with acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate
  - Adults with chronic pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate
- Limitations of Use
  - Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve morphine sulfate products for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or opioid combination products):
    - Have not been tolerated or are not expected to be tolerated.
    - Have not provided adequate analgesia or are not expected to provide adequate analgesia.

Nucynta (tapentadol)

Nucynta (tapentadol) tablets are indicated for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate in adults.

- Limitations of Use
  - Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve Nucynta (tapentadol) oral solution and tablets for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or opioid combination products):
    - Have not been tolerated or are not expected to be tolerated.
    - Have not provided adequate analgesia or are not expected to provide adequate analgesia.

Oxaydo (oxycodone hydrochloride)

Oxaydo (oxycodone hydrochloride) is indicated for the management of acute and chronic pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

- Limitations of Use
  - Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve Oxaydo (oxycodone hydrochloride) for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or opioid combination products):
    - Have not been tolerated or are not expected to be tolerated.
    - Have not provided adequate analgesia or are not expected to provide adequate analgesia.

Oxycodone Hydrochloride

- Capsules and Tablets
  - Oxycodone hydrochloride capsules and tablets are indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.
- Oral Solution
  - Oxycodone Hydrochloride Oral Solution is indicated in adults for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.
  - Oxycodone Hydrochloride Oral Solution 100 mg per 5 mL (20 mg/mL) is indicated for the relief of pain in opioid-tolerant patients.
- Limitations of Use
  - Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve oxycodone hydrochloride capsules, oral concentrate, oral solution, and tablets for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or opioid combination products):
    - Have not been tolerated or are not expected to be tolerated.
    - Have not provided adequate analgesia or are not expected to provide adequate analgesia.

Oxymorphone Hydrochloride

Oxymorphone hydrochloride tablets are indicated for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

- Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve oxymorphone hydrochloride tablets for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or opioid combination products):
  - Have not been tolerated or are not expected to be tolerated.
  - Have not provided adequate analgesia or are not expected to provide adequate analgesia.

Pentazocine/Naloxone

Pentazocine and naloxone tablets are indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

- Limitations of Use
  - Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve pentazocine and naloxone tablets for use in patients for whom alternative treatment options (e.g., non-opioid analgesics):
    - Have not been tolerated or are not expected to be tolerated.
    - Have not provided adequate analgesia or are not expected to provide adequate analgesia.

Qdolo (tramadol hydrochloride)

Qdolo is indicated in adults for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

- Limitations of Use
  - Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve Qdolo for use in patients for whom alternative treatment options [e.g., non-opioid analgesics]:
    - Have not been tolerated or are not expected to be tolerated.
    - Have not provided adequate analgesia or are not expected to provide adequate analgesia.

RoxyBond (oxycodone hydrochloride)

RoxyBond (oxycodone hydrochloride) is indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

- Limitations of Use
  - Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve RoxyBond (oxycodone hydrochloride) for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or opioid combination products):
    - Have not been tolerated or are not expected to be tolerated.
    - Have not provided adequate analgesia or are not expected to provide adequate analgesia.

Tramadol

Oral Solution and Tablets

Tramadol oral solution and tablets are indicated in adults for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

- Limitations of Use
  - Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve tramadol for use in patients for whom alternative treatment options (e.g., non-opioid analgesics):
    - Have not been tolerated or are not expected to be tolerated.
    - Have not provided adequate analgesia or are not expected to provide adequate analgesia.

Ultram (tramadol hydrochloride)

Ultram (tramadol hydrochloride) tablets are indicated in adults for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

- Limitations of Use
  - Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve Ultram (tramadol hydrochloride) tablets for use in patients for whom alternative treatment options [e.g., non-opioid analgesics]:

- Have not been tolerated or are not expected to be tolerated,
- Have not provided adequate analgesia or are not expected to provide adequate analgesia.

POLICY

Program Description

Neither acute pain duration limits nor quantity limits apply if the patient has a drug in claims history in the past year that indicates the patient is being treated for cancer or sickle cell disease. In addition, neither acute pain duration limits nor quantity limits will apply if a prescription claim is submitted with an ICD 10 diagnosis code indicating cancer, sickle cell disease, or palliative care, if the patient has an ICD 10 diagnosis code indicating cancer or palliative care in their member health profile in the past 365 days, if the patient has a history of an ICD 10 diagnosis code indicating sickle cell disease in their member health profile, or if a prescription claim is submitted using a hospice patient residence code.

Acute Pain Duration Limit

The acute pain duration limit portion of this program applies to patients identified with potential first fills of immediate-release opioid prescriptions for the treatment of non-cancer, non-sickle cell, non-hospice, and non-palliative care related pain. A first fill is defined as at least a 7-day supply of an immediate-release (IR) or extended-release (ER) opioid agent indicated for the management of pain within prescription claim history during the past 90 days.

If the patient does not have at least a 7-day supply of an IR or ER opioid agent indicated for the management of pain within prescription claim history in the past 90 days (i.e., this is the patient's first fill of an opioid) and the incoming prescription drug is being filled for more than a 7 day supply, then the claim will reject with a message indicating that the patient can receive a 7 day supply or submit a prior authorization (PA) for additional quantities. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit. If the incoming prescription drug is being filled for less than a 7 day supply, then the initial quantity limit criteria will apply (see Column A and Column B in the Opioid Analgesics IR Quantity Limits Chart below).

Initial Quantity Limit

Morphine milligram equivalent (MME) quantity limits for IR opioids provide coverage for an initial amount of a monthly quantity that corresponds to 90 MME or less per day. Coverage is provided for up to the initial quantity limit per Column A and Column B in the Opioid Analgesics IR Quantity Limits Chart below.

Prior authorization review is required to determine coverage for additional quantities above the initial limit.

Post limit quantities are set not to exceed a monthly quantity that corresponds to 200 MME per day. For patients with no prescription claims of a cancer drug or a sickle cell disease drug in the past 365 days, no ICD 10 diagnosis code indicating cancer, sickle cell disease, or palliative care submitted with their prescription claim, no ICD 10 diagnosis code indicating cancer or palliative care in the member health profile in the past 365 days, no history of an ICD 10 diagnosis code indicating sickle cell disease in their member health profile, or no hospice patient residence code submitted with their prescription claim who are identified through the prior authorization criteria as having cancer, sickle cell disease, a terminal condition or pain being managed through hospice or palliative care, post limit quantities will not apply.

*Acute Pain Duration Limit logic will apply first, followed by initial quantity limit logic.

Screenout Logic

If the patient has filled a prescription **for at least a 1-day supply of a drug indicating the patient is being treated for cancer or sickle cell disease within the past 365 days** under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit.

If a claim is submitted with an ICD 10 diagnosis code indicating cancer, sickle cell disease, or palliative care under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit.

If the patient has an ICD 10 diagnosis code indicating cancer or palliative care in their member health profile in the past 365 days, then the requested drug will be paid under that prescription benefit.

If the patient has any history of an ICD 10 diagnosis code indicating sickle cell disease in their member health profile, then the requested drug will be paid under that prescription benefit.

If a claim is submitted using a hospice patient residence code under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit.

For patients with no prescription claims of a cancer drug or a sickle cell disease drug in the past 365 days, no ICD 10 diagnosis code indicating cancer, sickle cell disease, or palliative care submitted with their prescription claim, no ICD 10 diagnosis code indicating cancer or palliative care in their member health profile in the past 365 days, no history of an ICD 10 diagnosis code indicating sickle cell disease in their member health profile, or no hospice patient residence code submitted with their prescription claim:
If the patient has filled a prescription **for at least an 8-day supply of an immediate-release (IR) or extended-release (ER) opioid agent indicated for the management of pain within prescription claim history in the past 90 days** under a prescription benefit administered by CVS Caremark, then the initial quantity limit criteria will apply (see Column A and Column B in the Opioid Analgesics IR Quantity Limits Chart below).

If the patient does not have at least an 8-day supply of an IR or ER opioid agent indicated for the management of pain within prescription claim history in the past 90 days (i.e., this is the patient's first fill of an opioid) and the incoming prescription drug is being filled for more than a 7-day supply, then the claim will reject with a message indicating that the patient can receive a 7-day supply (until 7-days of therapy in a 90-day period have been filled) or submit a prior authorization (PA) for additional quantities. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit. If the incoming prescription drug is being filled for less than a 7-day supply, then the initial quantity limit criteria will apply (see Column A and Column B in the Opioid Analgesics IR Quantity Limits Chart below). If the patient is exceeding 7 days of opioid therapy for the first time in a 90-day period, then the claim will reject with a message indicating that the patient must submit a prior authorization (PA) for additional quantities. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

Limit Criteria*
Neither acute pain duration limits nor quantity limits apply if the patient has a drug in claims history in the past year that indicates the patient is being treated for cancer or sickle cell disease. In addition, neither acute pain duration limits nor quantity limits will apply if a prescription claim is submitted with an ICD 10 diagnosis code indicating cancer, sickle cell disease, or palliative care, if the patient has an ICD 10 diagnosis code indicating cancer or palliative care in their member health profile in the past 365 days, if the patient has an ICD 10 diagnosis code indicating sickle cell disease in their member health profile, or if a prescription claim is submitted using a hospice patient residence code.

Acute Pain Duration Limit:
The acute pain duration limit portion of this program applies to patients identified with potential first fills of immediate-release opioid prescriptions for the treatment of non-cancer, non-sickle cell, non-hospice, and non-palliative care related pain. Patients are limited to a maximum of a 7-day supply per fill up to 7 days of therapy in a 90-day period. When the patient exceeds 7 days of opioid therapy for the first time in a 90-day period, prior authorization is required.

If the patient does not have at least an 8-day supply of an IR or ER opioid agent indicated for the management of pain within prescription claim history in the past 90 days (i.e., this is the patient's first fill of an opioid) and the incoming prescription drug is being filled for more than a 7-day supply, then the claim will reject with a message indicating that the patient can receive a 7-day supply (until 7-days of therapy in a 90-day period have been filled).

A prior authorization (PA) may be submitted for additional quantities. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit. If the incoming prescription drug is being filled for less than a 7-day supply, then the initial quantity limit criteria will apply until 7 days of therapy in a 90-day period have been filled. (see Column A and Column B in the Opioid Analgesics IR Quantity Limits Chart below). If the patient is exceeding 7 days of opioid therapy for the first time in a 90-day period, then the claim will reject with a message indicating that the patient must submit a prior authorization (PA) for additional quantities. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

Initial Quantity Limit:

Morphine milligram equivalent (MME) quantity limits for immediate-release opioids provide coverage for an initial amount of a monthly quantity that corresponds to 90 MME or less per day. Coverage is provided for up to the initial quantity limit per Column A and Column B in the Opioid Analgesics IR Quantity Limits Chart below. Prior authorization review is required to determine coverage for additional quantities above the initial limit.

*Acute Pain Duration Limit logic will apply first, followed by initial quantity limit logic.

Coverage Criteria

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for pain associated with cancer, sickle cell disease, a terminal condition, or pain being managed through hospice or palliative care

OR

- The patient can safely take the requested dose based on their history of opioid use. [Note: The lowest effective dosage should be prescribed for opioid naïve patients.]

  AND

- The patient has been evaluated and the patient will be monitored regularly for the development of opioid use disorder

  AND

  - The requested drug is being prescribed for moderate to severe CHRONIC pain where use of an opioid analgesic is appropriate. [Note: Chronic pain is generally defined as pain that typically lasts greater than 3 months.]

    AND

  - The patient's pain will be reassessed in the first month after the initial prescription or any dose increase AND every 3 months thereafter to ensure that clinically meaningful improvement in pain and function outweigh risks to patient safety

    OR

  - The patient requires extended treatment beyond 7 days for moderate to severe ACUTE pain where use of an opioid analgesic is appropriate

Quantity Limits may apply.

Opioid Analgesics IR Quantity Limits Chart

Opioid Analgesics IR Quantity Limits Chart
Coverage is provided without prior authorization (for patients not identified as potential first fills) for a 30-day or 90-day supply of an immediate-release opioid for a quantity that corresponds to ≤ 90 MME/day. Coverage for quantities that correspond to ≤ 200 MME/day for a 30-day or 90-day supply is provided through prior authorization when criteria for approval are met.

These quantity limits should accumulate across all drugs of the same unit limit (i.e., drugs with 30 units accumulate together, drugs with 60 units accumulate together, etc).					
		COLUMN A	**COLUMN B**	**COLUMN C**	**COLUMN D**
Drug/Strength**	**Labeled Dosing**	**Initial 1 Month Limit* ≤ 90 MME/day (per 25 days)**	**Initial 3 Month Limit* ≤ 90 MME/day (per 75 days)**	**Post 1 Month Limit* ≤ 200 MME/day (per 25 days)**	**Post 3 Month Limit* ≤ 200 MME/day (per 75 days)**
Codeine sulfate tab 15 mg	q4h, Max Daily Dose 360 mg	42 tabs/month‡ 6 tabs/day (13.5 MME/day)	Does Not Apply‡	84 tabs/month‡ 6 tabs/day (13.5 MME/day)	Use Column C
Codeine sulfate tab 30 mg	q4h, Max Daily Dose 360 mg	42 tabs/month‡ 6 tabs/day (27 MME/day)	Does Not Apply‡	84 tabs/month‡ 6 tabs/day (27 MME/day)	Use Column C
Codeine sulfate tab 60 mg	q4h, Max Daily Dose 360 mg	42 tabs/month‡ 6 tabs/day (54 MME/day)	Does Not Apply‡	84 tabs/month‡ 6 tabs/day (54 MME/day)	Use Column C
Hydromorphone oral soln 5 mg/5 mL (1 mg/mL)	q3-6h	480 mL/month 16 mL/day (80 MME/day)	1440 mL/3 months 16 mL/day (80 MME/day)	1200 mL/month 40 mL/day (200 MME/day)	3600 mL/3 months 40 mL/day (200 MME/day)
Hydromorphone supp 3 mg	q6-8h	120 supps/month 4 supps/day (60 MME/day)	360 supps/3 months 4 supps/day (60 MME/day)	180 supps/month 6 supps/day (90 MME/day)	540 supps/3 months 6 supps/day (90 MME/day)
Hydromorphone tab 2 mg	q4-6h	180 tabs/month 6 tabs/day (60 MME/day)	540 tabs/3 months 6 tabs/day (60 MME/day)	270 tabs/month 9 tabs/day (90 MME/day)	810 tabs/3 months 9 tabs/day (90 MME/day)
Hydromorphone tab 4 mg	q4-6h	120 tabs/month 4 tabs/day (80 MME/day)	360 tabs/3 months 4 tabs/day (80 MME/day)	180 tabs/month 6 tabs/day (120 MME/day)	540 tabs/3 months 6 tabs/day

					(120 MME/day)
Hydromorphone tab 8 mg	q4-6h	60 tabs/month 2 tabs/day (80 MME/day)	180 tabs/3 months 2 tabs/day (80 MME/day)	90 tabs/month 3 tabs/day (120 MME/day)	270 tabs/3 months 3 tabs/day (120 MME/day)
Levorphanol tab 1 mg	q6-8h	120 tabs/month 4 tabs/day (44 MME/day)	360 tabs/3 months 4 tabs/day (44 MME/day)	180 tabs/month 6 tabs/day (66 MME/day)	540 tabs/3 months 6 tabs/day (66 MME/day)
Levorphanol tab 2 mg	q6-8h	120 tabs/month 4 tabs/day (88 MME/day)	360 tabs/3 months 4 tabs/day (88 MME/day)	180 tabs/month 6 tabs/day (132 MME/day)	540 tabs/3 months 6 tabs/day (132 MME/day)
Levorphanol tab 3 mg	q6-8h	60 tabs/month 2 tabs/day (66 MME/day)	180 tabs/3 months 2 tabs/day (66 MME/day)	180 tabs/month 6 tabs/day (198 MME/day)	540 tabs/3 months 6 tabs/day (198 MME/day)
Meperidine oral soln 50 mg/5 mL	q3-4h	90 mL/month**** 30 mL/day (30 MME/day)	Does Not Apply****	120 mL/month**** 30 mL/day (30 MME/day)	Use Column C
Meperidine tab 50 mg	q3-4h	18 tabs/month**** 6 tabs/day (30 MME/day)	Does Not Apply****	24 tabs/month**** 6 tabs/day (30 MME/day)	Use Column C
Morphine sulfate (conc) oral soln 20 mg/mL (100 mg/5 mL)	q4h	135 mL/month 4.5 mL/day (90 MME/day)	405 mL/3 months 4.5 mL/day (90 MME/day)	270 mL/month 9 mL/day (180 MME/day)	810 mL/3 months 9 mL/day (180 MME/day)
Morphine sulfate oral soln 10 mg/5 mL	q4h	900 mL/month 30 mL/day (60 MME/day)	2700 mL/3 months 30 mL/day (60 MME/day)	1350 mL/month 45 mL/day (90 MME/day)	4050 mL/3 months 45 mL/day (90 MME/day)
Morphine sulfate oral soln 20 mg/5 mL	q4h	675 mL/month 22.5 mL/day (90 MME/day)	2025 mL/3 months 22.5 mL/day (90 MME/day)	1350 mL/month 45 mL/day (180 MME/day)	4050 mL/3 months 45 mL/day (180 MME/day)

Morphine sulfate supp 5 mg	q4h	180 supps/month 6 supps/day (30 MME/day)	540 supps/3 month 6 supps/day (30 MME/day)	270 supps/month 9 supps/day (45 MME/day)	810 supps/3 months 9 supps/day (45 MME/day)
Morphine sulfate supp 10 mg	q4h	180 supps/month 6 supps/day (60 MME/day)	540 supps/3 month 6 supps/day (60 MME/day)	270 supps/month 9 supps/day (90 MME/day)	810 supps/3 months 9 supps/day (90 MME/day)
Morphine sulfate supp 20 mg	q4h	120 supps/month 4 supps/day (80 MME/day)	360 supps/3 months 4 supps/day (80 MME/day)	270 supps/month 9 supps/day (180 MME/day)	810 supps/3 months 9 supps/day (180 MME/day)
Morphine sulfate supp 30 mg	q4h	90 supps/month 3 supps/day (90 MME/day)	270 supps/3 months 3 supps/day (90 MME/day)	180 supps/month 6 supps/day (180 MME/day)	540 supps/3 months 6 supps/day (180 MME/day)
Morphine sulfate tab 15 mg	q4h	180 tabs/month 6 tabs/day (90 MME/day)	540 tabs/3 months 6 tabs/day (90 MME/day)	270 tabs/month 9 tabs/day (135 MME/day)	810 tabs/3 months 9 tabs/day (135 MME/day)
Morphine sulfate tab 30 mg	q4h	90 tabs/month 3 tabs/day (90 MME/day)	270 tabs/3 months 3 tabs/day (90 MME/day)	180 tabs/month 6 tabs/day (180 MME/day)	540 tabs/3 months 6 tabs/day (180 MME/day)
Oxycodone cap 5 mg	q4-6h	180 caps/month 6 caps/day (45 MME/day)	540 caps/3 months 6 caps/day (45 MME/day)	270 caps/month 9 caps/day (67.5 MME/day)	810 caps/3 months 9 caps/day (67.5 MME/day)
Oxycodone oral concentrate 100 mg/5 mL (20 mg/mL)	q4-6h	90 mL/month 3 mL/day (90 MME/day)	270 mL/3 months 3 mL/day (90 MME/day)	180 mL/month 6 mL/day (180 MME/day)	540 mL/3 months 6 mL/day (180 MME/day)
Oxycodone soln 5 mg/5 mL	q4-6h	900 mL/month 30 mL/day (45 MME/day)	2700 mL/3 months 30 mL/day (45 MME/day)	2700 mL/ month 90 mL/day (135 MME/day)	8100 mL/3 months 90 mL/day (135 MME/day)

Oxycodone tab 5 mg	q4-6h	180 tabs/month 6 tabs/day (45 MME/day)	540 tabs/3 months 6 tabs/day (45 MME/day)	270 tabs/month 9 tabs/day (67.5 MME/day)	810 tabs/3 months 9 tabs/day (67.5 MME/day)
Oxycodone (Oxaydo) tab 5 mg	q4-6h	180 tabs/month 6 tabs/day (45 MME/day)	540 tabs/3 months 6 tabs/day (45 MME/day)	270 tabs/month 9 tabs/day (67.5 MME/day)	810 tabs/3 months 9 tabs/day (67.5 MME/day)
Oxycodone (RoxyBond) tab 5 mg	q4-6h	180 tabs/month 6 tabs/day (45 MME/day)	540 tabs/3 months 6 tabs/day (45 MME/day)	270 tabs/month 9 tabs/day (67.5 MME/day)	810 tabs/3 months 9 tabs/day (67.5 MME/day)
Oxycodone (Oxaydo) tab 7.5 mg	q4-6h	180 tabs/month 6 tabs/day (67.5 MME/day)	540 tabs/3 months 6 tabs/day (67.5 MME/day)	270 tabs/month 9 tabs/day (101.25 MME/day)	810 tabs/3 months 9 tabs/day (101.25 MME/day)
Oxycodone tab 10 mg	q4-6h	180 tabs/month 6 tabs/day (90 MME/day)	540 tabs/3 months 6 tabs/day (90 MME/day)	270 tabs/month 9 tabs/day (135 MME/day)	810 tabs/3 months 9 tabs/day (135 MME/day)
Oxycodone tab 15 mg	q4-6h	120 tabs/month 4 tabs/day (90 MME/day)	360 tabs/3 months 4 tabs/day (90 MME/day)	180 tabs/month 6 tabs/day (135 MME/day)	540 tabs/3 months 6 tabs/day (135 MME/day)
Oxycodone (RoxyBond) tab 15 mg	q4-6h	120 tabs/month 4 tabs/day (90 MME/day)	360 tabs/3 months 4 tabs/day (90 MME/day)	180 tabs/month 6 tabs/day (135 MME/day)	540 tabs/3 months 6 tabs/day (135 MME/day)
Oxycodone tab 20 mg	q4-6h	90 tabs/month 3 tabs/day (90 MME/day)	270 tabs/3 months 3 tabs/day (90 MME/day)	180 tabs/month 6 tabs/day (180 MME/day)	540 tabs/3 months 6 tabs/day (180 MME/day)
Oxycodone tab 30 mg	q4-6h	60 tabs/month 2 tabs/day (90 MME/day)	180 tabs/3 months 2 tabs/day (90 MME/day)	120 tabs/month 4 tabs/day (180 MME/day)	360 tabs/3 months 4 tabs/day

					(180 MME/day)
Oxycodone (RoxyBond) tab 30 mg	q4-6h	60 tabs/month 2 tabs/day (90 MME/day)	180 tabs/3 months 2 tabs/day (90 MME/day)	120 tabs/month 4 tabs/day (180 MME/day)	360 tabs/3 months 4 tabs/day (180 MME/day)
Oxymorphone tab 5 mg	q4-6h	180 tabs/month 6 tabs/day (90 MME/day)	540 tabs/3 months 6 tabs/day (90 MME/day)	360 tabs/month 12 tabs/day (180 MME/day)	1080 tabs/3 months 12 tabs/day (180 MME/day)
Oxymorphone tab 10 mg	q4-6h	90 tabs/month 3 tabs/day (90 MME/day)	270 tabs/3 months 3 tabs/day (90 MME/day)	180 tabs/month 6 tabs/day (180 MME/day)	540 tabs/3 months 6 tabs/day (180 MME/day)
Pentazocine/naloxone 50/0.5 mg	q3-4h, Total daily dose should not exceed 12 tablets.	120 tabs/month*** 4 tabs/day (74 MME/day)	Does Not Apply ***	300 tabs/month*** 10 tabs/day (185 MME/day)	Use Column C
Tapentadol tab 50 mg	q4-6h, Max daily dose is 700 mg on the first day and 600 mg on subsequent days.	120 tabs/month 4 tabs/day (80 MME/day)	360 tabs/3 months 4 tabs/day (80 MME/day)	240 tabs/month 8 tabs/day (160 MME/day)	720 tabs/3 months 8 tabs/day (160 MME/day)
Tapentadol tab 75 mg	q4-6h, Max daily dose is 700 mg on the first day and 600 mg on subsequent days.	90 tabs/month 3 tabs/day (90 MME/day)	270 tabs/3 months 3 tabs/day (90 MME/day)	180 tabs/month 6 tabs/day (180 MME/day)	540 tabs/3 months 6 tabs/day (180 MME/day)
Tapentadol tab 100 mg	q4-6h, Max daily dose is 700 mg on the first day and 600 mg on subsequent days.	60 tabs/month 2 tabs/day (80 MME/day)	180 tabs/3 months 2 tabs/day (80 MME/day)	120 tabs/month 4 tabs/day (160 MME/day)	360 tabs/3 months 4 tabs/day (160 MME/day)
Tramadol oral soln 5 mg/mL	q4-6h, Max Daily Dose 400 mg	1800 mL/month 60 mL/day (60 MME/day)	5400 mL/3 months 60 mL/day (60 MME/day)	2400 mL/month 80 mL/day (80 MME/day)	7200 mL/3 months 80 mL/day (80 MME/day)
Tramadol (Qdolo) oral soln 5 mg/mL	q4-6h, Max Daily Dose 400 mg	1800 mL/month 60 mL/day	5400 mL/3 months 60 mL/day	2400 mL/month 80 mL/day	7200 mL/3 months 80 mL/day

		(60 MME/day)	(60 MME/day)	(80 MME/day)	(80 MME/day)
Tramadol 50 mg	q4-6h, Max Daily Dose 400 mg	180 tabs/month 6 tabs/day (60 MME/day)	540 tabs/3 months 6 tabs/day (60 MME/day)	240 tabs/month 8 tabs/day (80 MME/day)	720 tabs/3 months 8 tabs/day (80 MME/day)
Tramadol 100 mg	q4-6h, Max Daily Dose 400 mg	90 tabs/month 3 tabs/day (60 MME/day)	270 tabs/3 months 3 tabs/day (60 MME/day)	120 tabs/month 4 tabs/day (80 MME/day)	360 tabs/3 months 4 tabs/day (80 MME/day)

**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing. Limits are set up both as quantity versus time and daily dose edits.*

***The limit criteria apply to both brand and generic, if available.*

**** This drug is indicated for short-term acute use; therefore, the 30-day limit will be the same as the 90-day limit. The intent is for prescriptions of the requested drug to be filled one month at a time, even if filled at mail order; there should be no 3 month supplies filled.*

*****Due to risk of accumulation, the initial quantity limit will be set at a quantity that corresponds to a 3-day supply. The post limit quantity will be set at a quantity that corresponds to a 4-day supply. This drug is indicated for short-term acute use; therefore, the 30-day limit will be the same as the 90-day limit. The intent is for prescriptions of the requested drug to be filled one month at a time, even if filled at mail order; there should be no 3 month supplies filled.*

‡ *The initial quantity limit for codeine will be set at a quantity that corresponds to a one-week supply. The post limit quantity will be set at a quantity that corresponds to a two-week supply. This drug is indicated for short-term acute use; therefore, the 30-day limit will be the same as the 90-day limit. The intent is for prescriptions of the requested drug to be filled one month at a time, even if filled at mail order; there should be no 3 month supplies filled.*

CLINICAL RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Codeine sulfate tablets are indicated for the management of mild to moderate pain, where treatment with an opioid is appropriate and for which alternative treatments are inadequate.[1] Dilaudid (hydromorphone hydrochloride), hydromorphone hydrochloride suppositories, levorphanol tartrate, oxycodone hydrochloride capsules and tablets, oxycodone hydrochloride oral solution, pentazocine/naloxone, Qdolo (tramadol hydrochloride), RoxyBond (oxycodone hydrochloride), tramadol hydrochloride and Ultram (tramadol hydrochloride) are indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.[2-5, 12-14, 16-20] Oxycodone hydrochloride oral solution 100 mg per 5 mL (20 mg/mL) is indicated for the relief of pain in opioid-tolerant patients.[14] Meperidine hydrochloride, Nucynta (tapentadol), and oxymorphone hydrochloride are indicated for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.[6,10,15] Morphine sulfate oral solution 2 mg/mL and 4 mg/mL, morphine sulfate suppositories and morphine sulfate tablets are indicated for the management of acute and chronic pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate in adult patients.[7-9] Morphine sulfate oral solution 2 mg/mL and 4 mg/mL are also indicated for acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate in pediatric patients 2 years of age and older. Morphine sulfate oral solution 100 mg/5 mL is indicated for the relief of acute and chronic pain in opioid-tolerant adult patients.[7] Oxaydo (oxycodone hydrochloride) is indicated for the management of acute and chronic pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.[11] Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve immediate-release opioids for use in patients for whom alternative treatment options [e.g., non-opioid analgesics or opioid combination products]: 1) have not been

tolerated or are not expected to be tolerated, or 2) have not provided adequate analgesia or are not expected to provide adequate analgesia.[1-22]

If the patient has filled a prescription for at least a 1-day supply of a drug indicating the patient is being treated for cancer or sickle cell disease (SCD) within the past 365 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit.

If a claim is submitted with an ICD 10 diagnosis code indicating cancer, sickle cell disease, or palliative care under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit.

If the patient has an ICD 10 diagnosis code indicating cancer or palliative care in their member health profile in the past 365 days, then the requested drug will be paid under that prescription benefit.

If the patient has any history of an ICD 10 diagnosis code indicating sickle cell disease in their member health profile, then the requested drug will be paid under that prescription benefit.

If a claim is submitted using a hospice patient residence code under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit.
For patients with no prescription claims of a cancer drug or a sickle cell disease drug in the past 365 days, no ICD 10 diagnosis code indicating cancer, sickle cell disease, or palliative care submitted with their prescription claim, no ICD 10 diagnosis code indicating cancer or palliative care in their member health profile in the past 365 days, no history of an ICD 10 diagnosis code indicating sickle cell disease in their member health profile, or no hospice patient residence code submitted with their prescription claim:
If the patient has filled a prescription for at least an 8-day supply of an immediate-release (IR) or extended-release (ER) opioid agent indicated for the management of pain within prescription claim history in the past 90 days under a prescription benefit administered by CVS Caremark, then the initial quantity limit criteria will apply (see Column A and Column B in the Opioid Analgesics IR Quantity Limits Chart below).
If the patient does not have at least an 8-day supply of an IR or ER opioid agent indicated for the management of pain within prescription claim history in the past 90 days (i.e., this is the patient's first fill of an opioid) and the incoming prescription drug is being filled for more than a 7-day supply, then the claim will reject with a message indicating that the patient can receive a 7-day supply (until 7-days of therapy in a 90-day period have been filled) or submit a prior authorization (PA) for additional quantities. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit. If the incoming prescription drug is being filled for less than a 7-day supply, then the initial quantity limit criteria will apply (see Column A and Column B in the Opioid Analgesics IR Quantity Limits Chart below).

The Centers for Disease Control and Prevention (CDC) Clinical Practice Guideline for Prescribing Opioids for Pain provides recommendations for clinicians providing pain care, including those prescribing opioids for outpatients aged ≥ 18 years. The recommendations do not apply to pain related to sickle cell disease or cancer or to patients receiving palliative or end-of-life care.[26] ***The*** National Comprehensive Cancer Network (NCCN) guidelines for Adult Cancer Pain recommend for continuous pain, it is appropriate to give pain medication on a regular schedule with supplemental doses for breakthrough pain. Add an extended-release or long-acting formulation to provide background analgesia for control of chronic persistent pain controlled on stable doses of short-acting opioids. Allow rescue doses of short-acting opioids up to every 1 hour as needed.[24] The NCCN Palliative Care pain management recommendation is to treat according to NCCN guidelines for adult cancer pain.[23] For patients with no prescription claims of a cancer drug in the past 365 days, no ICD 10 diagnosis code indicating cancer or palliative care submitted with their prescription claim, no ICD 10 diagnosis code indicating cancer or palliative care in their member health profile in the past 365 days, or no hospice patient residence code submitted with their prescription claim who are identified through the prior authorization criteria as having cancer, a terminal condition, or pain being managed through hospice or palliative care, acute pain duration limits and post limit quantities will not apply.

According to the National Heart, Lung, and Blood Institute's (NHLBI) guidelines for Sickle Cell Disease (SCD), pain is the most common symptom of SCD. Pain can be acute, chronic, or an acute episode superimposed on chronic pain. Recurrent acute pain crises (also known as vaso-occlusive crises) are the most common manifestation of SCD. Chronic pain is also one of the most common chronic complications of SCD. Pain management must be guided by patient report of severity. No biomarkers or imaging studies can validate pain or assess its severity. Medications used to treat SCD-related pain should be tailored to the individual. For pain that is not relieved by nonsteroidal anti-inflammatory drugs (NSAIDs) or other measures, either short-acting or long-acting opioids may be used to manage pain in SCD.[28] For patients with no prescription claims of a sickle cell disease drug in the past 365 days, no ICD 10 diagnosis code indicating sickle cell disease submitted with their prescription claim, or no history of an ICD 10 diagnosis code indicating sickle cell disease in their member health profile who are identified through the prior authorization criteria as having sickle cell disease, acute pain duration limits and post limit quantities will not apply.

Evidence exists from observational studies of an association between opioid use for acute pain and long-term opioid use. Opioids are sometimes needed for treatment of acute pain. When the diagnosis and severity of acute pain warrant use of opioids, clinicians should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. For many common causes of nontraumatic, nonsurgical pain, when opioids are needed, a few days or less are often sufficient, and shorter courses can minimize the need to taper opioids to prevent withdrawal symptoms at the end of a course of opioids. Data suggest that pain improves within days for many patients with common types of acute pain in primary care or emergency department settings. Analysis of nationwide U.S. commercial insurance claims in 2014 found median durations of initial opioid analgesic prescriptions for acute pain indications in primary care settings were 4–7 days, suggesting that in most cases, clinicians considered an initial opioid prescription of 4-7 days duration sufficient.[26] Coverage is provided for up to 7 days initially to provide an amount sufficient for the treatment of acute pain.

Risks of opioid use, including risk for overdose and overdose death, increase continuously with dosage, and there is no single dosage threshold below which risks are eliminated. When opioids are initiated for opioid-naïve patients with acute, subacute or chronic pain, clinicians should prescribe the lowest effective dosage. For patients not already taking opioids, the lowest effective dose can be determined using product labeling as a starting point with calibration as needed based on the severity of pain and other clinical factors such as renal or hepatic insufficiency. If opioids are continued for subacute or chronic pain, clinicians should use caution when prescribing opioids at any dosage and should generally avoid dosage increases when possible.[26]

Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risks for opioid-related harms and discuss risk with patients. Clinicians should reevaluate patients who are at higher risk for opioid use disorder or overdose (e.g., patients with depression or other mental conditions, a history of substance use disorder, a history of overdose, taking ≥ 50 MME/day, or taking other central nervous system depressants with opioids) more frequently than every 3 months. Clinicians should regularly screen all patients for these conditions, which can change during the course of treatment.[26]

Clinicians should evaluate benefits and risks with patients within 1 to 4 weeks of starting opioid therapy for subacute or chronic pain or of dose escalation. Clinicians should regularly reevaluate benefits and risks of continued opioid therapy with patients. Clinicians should regularly reassess all patients receiving long-term opioid therapy, with a suggested interval of every 3 months or more frequently for most patients. If benefits do not outweigh risks of continued opioid therapy, clinicians should optimize other therapies and work closely with patients to gradually taper opioids to lower dosages or, if warranted based on the individual circumstances of the patient, appropriately taper and discontinue opioids.[26]

The CDC Clinical Practice Guideline for Prescribing Opioids for Pain recommends that when opioids are initiated for opioid-naïve patients, clinicians should prescribe the lowest effective dosage. If opioids are continued, clinicians should use caution when prescribing opioids at any dosage, should carefully evaluate individual benefits and risks when considering increasing dosage, and should avoid increasing dosage above levels likely to yield diminishing returns in benefits relative to risks to patients. Many patients do not experience benefit in pain or

function from increasing opioid dosages to ≥ 50 morphine milliequivalents per day (MME/day) but are exposed to progressive increases in risk as dosage increases. Opioid dosages of 50-90 MME/day were associated with a minimally greater improvement in mean pain intensity compared with dosages of < 50 MME/day. Few trials evaluated opioid dosages of ≥ 90 MME/day.[26] The immediate-release opioid drug initial quantity limits are set to encompass the usual/starting dosage and frequency range recommendations in labeling without exceeding a monthly quantity that corresponds to 90 MME/day. If the patient is requesting more than the initial quantity limit, then the system will reject with a message indicating that a prior authorization is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

The American Pain Society Opioid Treatment Guidelines state that a reasonable definition for high dose opioid therapy is >200 mg daily of oral morphine (or equivalent).[25] The immediate-release opioid drug post limit quantities are set to encompass the usual dosage and frequency range recommendations in labeling, or up to 1.5 times the initial quantity limit, without exceeding a monthly quantity that corresponds to 200 MME/day to promote optimization of pain management, safe and effective use, and to reduce misuse, abuse, and overdose.

Although meperidine is commonly used for acute pain relief, use of this drug as first-line opiate therapy is discouraged because of central excitatory toxicity of the metabolite (normeperidine). Because of extensive first-pass metabolism in the liver and resultant increased formation of normeperidine, the risk of excitatory toxicity is increased with oral administration of meperidine. Therefore, oral therapy is discouraged. Use of meperidine for chronic pain is discouraged because of its short duration of effect and risk of accumulation. Meperidine should be limited to short-term (i.e., a few days) because of the risk of accumulation of the toxic normeperidine metabolite with repeated or large doses.[21] The initial quantity limit for meperidine will be set at a quantity that corresponds to a 72 hour supply (allows for weekend coverage, if necessary). The post limit quantity will be set at a quantity that corresponds to a 96 hour supply, allowing one additional day of therapy beyond the initial quantity limit.

When prescribing codeine, healthcare providers should choose the lowest effective dose for the shortest period of time.[1] The limit for codeine is set reflective of its questionable role in chronic or moderate to severe pain management as compared to other opioid medications. The initial quantity limit for codeine will be set at a quantity that corresponds to a one- week supply. The post limit quantity will be set at a quantity that corresponds to a two-week supply.

Pentazocine is not commonly used in clinical practice due to the occurrence of dysphoric reactions and its relatively short duration of action.[27] According to the NCCN Guidelines for Adult Cancer Pain, mixed agonist-antagonist drugs (including pentazocine) have limited usefulness and are not recommended for the treatment of cancer pain.[24] The one month and three month limits for pentazocine/naloxone are set as the same based on these significant safety concerns.

Acute pain is usually sudden in onset and time limited (defined in the CDC clinical practice guideline as having a duration of <1 month) and often is caused by injury, trauma, or medical treatments such as surgery.[26] Therefore, the duration of approval for patients meeting coverage criteria for acute pain will be one month.

Unresolved acute pain or subacute pain (defined in the CDC clinical practice guideline as pain that has been present for 1-3 months) can evolve into chronic pain. Chronic pain typically lasts >3 months and can be the result of an underlying medical disease or conditional, injury, medical treatment, inflammation, or unknown cause. Clinical evidence reviews found insufficient evidence to determine long-term benefits of opioid therapy for chronic pain and found an increased risk for serious harms related to long-term opioid therapy that appears to be dose dependent. Compared with placebo, at short-term follow-up (1 to < 6 months) opioids were associated with small mean improvements in pain intensity. Some evidence indicates that improvement in pain is reduced with longer duration of opioid therapy. No placebo-controlled trial evaluated effectiveness of opioids at intermediate (6 to < 12 months) or long-term (≥ 12 months follow-up).[26] Therefore, the duration of approval for patients meeting coverage criteria for chronic pain will be 6 months.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

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POLICY HISTORY

Policy #: 05.02.38
Reviewed: April 2023
Revised: April 2023
Current Effective Date: July 1, 2023