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## DRUG POLICY

# 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.

##### **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 acute and chronic pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.
  - Morphine sulfate oral solution 100 mg per 5 mL (20 mg/mL) is indicated for the relief of acute and chronic pain in opioid-tolerant patients.
- Suppositories, Tablets
  - Morphine sulfate suppositories and 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.
- 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)**

- Oral Solution and Tablets
  - Nucynta (tapentadol) 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 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, Oral Concentrate, Oral Solution, and Tablets
  - Oxycodone hydrochloride capsules, oral concentrate, oral solution, 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 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.

### **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.

## **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).

#### 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  $\leq 90$  MME/day. Coverage for quantities that correspond to  $\leq 200$  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* $\leq 90$ MME/day (per 25 days)	Initial 3 Month Limit* $\leq 90$ MME/day (per 75 days)	Post 1 Month Limit* $\leq 200$ MME/day (per 25 days)	Post 3 Month Limit* $\leq 200$ MME/day (per 75 days)
Codeine sulfate tab 15 mg	q4h, Max Daily Dose 360 mg	42 tabs/month <sup>†</sup> 6 tabs/day (13.5 MME/day)	Does Not Apply <sup>†</sup>	84 tabs/month <sup>†</sup> 6 tabs/day (13.5 MME/day)	Use Column C
Codeine sulfate tab 30 mg	q4h, Max Daily Dose 360 mg	42 tabs/month <sup>†</sup> 6 tabs/day (27 MME/day)	Does Not Apply <sup>†</sup>	84 tabs/month <sup>†</sup> 6 tabs/day (27 MME/day)	Use Column C
Codeine sulfate tab 60 mg	q4h, Max Daily Dose 360 mg	42 tabs/month <sup>†</sup> 6 tabs/day (54 MME/day)	Does Not Apply <sup>†</sup>	84 tabs/month <sup>†</sup> 6 tabs/day (54 MME/day)	Use Column C
Hydromorphone oral soln 5 mg/5 mL (1 mg/mL)	q3-6h	600 mL/month 20 mL/day (80 MME/day)	1800 mL/3 months 20 mL/day (80 MME/day)	1500 mL/month 50 mL/day (200 MME/day)	4500 mL/3 months 50 mL/day (200 MME/day)
Hydromorphone supp 3 mg	q6-8h	120 supps/month 4 supps/day (48 MME/day)	360 supps/3 months 4 supps/day (48 MME/day)	180 supps/month 6 supps/day (72 MME/day)	540 supps/3 months 6 supps/day (72 MME/day)
Hydromorphone tab 2 mg	q4-6h	180 tabs/month	540 tabs/3 months	270 tabs/month	810 tabs/3 months

		6 tabs/day (48 MME/day)	6 tabs/day (48 MME/day)	9 tabs/day (72 MME/day)	9 tabs/day (72 MME/day)
Hydromorphone tab 4 mg	q4-6h	150 tabs/month 5 tabs/day (80 MME/day)	450 tabs/3 months 5 tabs/day (80 MME/day)	225 tabs/month 7.5 tabs/day (120 MME/day)	675 tabs/3 months 7.5 tabs/day (120 MME/day)
Hydromorphone tab 8 mg	q4-6h	60 tabs/month 2 tabs/day (64 MME/day)	180 tabs/3 months 2 tabs/day (64 MME/day)	90 tabs/month 3 tabs/day (96 MME/day)	270 tabs/3 months 3 tabs/day (96 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
Meperidine tab 100 mg	q3-4h	18 tabs/month**** 6 tabs/day (60 MME/day)	Does Not Apply****	24 tabs/month**** 6 tabs/day (60 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	405 mL/3 months 4.5 mL/day	270 mL/month 9 mL/day	810 mL/3 months 9 mL/day



		(90 MME/day)	(90 MME/day)	(180 MME/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/month 4 supps/day (80 MME/day)	270 supps/month 9 supps/day (180 MME/day)	810 supps/month 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)
Oxaydo 5 mg	q4-6h	180 tabs/month 6 tabs/day	540 tabs/3 months 6 tabs/day	270 tabs/month 9 tabs/day	810 tabs/3 months 9 tabs/day

		(45 MME/day)	(45 MME/day)	(67.5 MME/day)	(67.5 MME/day)
Oxaydo 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 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 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 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	180 tabs/3 months 2 tabs/day	120 tabs/month 4 tabs/day	360 tabs/3 months 4 tabs/day

		(90 MME/day)	(90 MME/day)	(180 MME/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
RoxyBond 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)
RoxyBond 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)
RoxyBond 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)
Tapentadol oral soln 20 mg/mL <sup>†</sup>	q4-6h, Max daily dose is 700 mg on the first day and 600 mg on subsequent days.	300 mL/month 10 mL/day (80 MME/day)	900 mL/3 months 10 mL/day (80 MME/day)	700 mL/month 23.33 mL/day (186.7 MME/day)	2100 mL/3 months 23.33 mL/day (186.7 MME/day)
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	90 tabs/month 3 tabs/day	270 tabs/3 months 3 tabs/day	180 tabs/month 6 tabs/day	540 tabs/3 months 6 tabs/day

	600 mg on subsequent days.	(90 MME/day)	(90 MME/day)	(180 MME/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 (30 MME/day)	5400 mL/3 months 60 mL/day (30 MME/day)	2400 mL/month 80 mL/day (40 MME/day)	7200 mL/month 80 mL/day (40 MME/day)
Tramadol 50 mg	q4-6h, Max Daily Dose 400 mg	180 tabs/month 6 tabs/day (30 MME/day)	540 tabs/3 months 6 tabs/day (30 MME/day)	240 tabs/month 8 tabs/day (40 MME/day)	720 tabs/3 months 8 tabs/day (40 MME/day)
Tramadol 100 mg	q4-6h, Max Daily Dose 400 mg	90 tabs/month 3 tabs/day (30 MME/day)	270 tabs/3 months 3 tabs/day (30 MME/day)	120 tabs/month 4 tabs/day (40 MME/day)	360 tabs/3 months 4 tabs/day (40 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.

† Available in 100 mL and 200 mL bottles. It is the discretion of the dispensing pharmacy to fill quantities per package size up to these quantity limits. In such cases the filling limit and day supply may be less than what is indicated.

‡ 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 is indicated for the management of mild to moderate pain, where treatment with an opioid is appropriate and for which alternative treatments are inadequate. Hydromorphone, levorphanol, oxycodone, pentazocine/naloxone, and tramadol are indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Morphine sulfate and Oxaydo are indicated for the management of acute and chronic pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Oxymorphone, meperidine, and tapentadol are indicated for the relief of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. 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.<sup>1-23</sup>

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 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:

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). 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.

The Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain provides recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, sickle cell disease, palliative care, and end-of-life care.<sup>27</sup> 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.<sup>25</sup> The NCCN

Palliative Care pain management recommendation is to treat according to NCCN guidelines for adult cancer pain.<sup>24</sup> 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.<sup>29</sup> For patients with no prescription claims of a sickle cell disease drug in the past 365 days, no history of an ICD 10 diagnosis code indicating sickle cell disease submitted with their prescription claim, or no 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.

According to the CDC Guideline for Prescribing Opioids for Chronic Pain, long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should not prescribe a greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.<sup>27</sup> Coverage is provided for up to 7 days initially to provide an amount sufficient for the treatment of acute pain.

Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, then clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.<sup>27</sup>

Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should consider history of overdose, history of substance use disorder, higher opioid dosages [ $\geq 50$  morphine milligram equivalents per day (MME/day)], or concurrent benzodiazepine use.<sup>27</sup>

The CDC Guideline for Prescribing Opioids for Chronic Pain recommends that when opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, carefully reassess evidence of individual benefits and risks when increasing dosage to  $\geq 50$  MME/day, and avoid increasing the dosage to  $\geq 90$  MME/day or carefully justify a decision to titrate the dosage to  $\geq 90$  MME/day.<sup>27</sup> 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).<sup>26</sup> 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 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.<sup>22</sup> 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.

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. When prescribing codeine, healthcare providers should choose the lowest effective dose for the shortest period of time. 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.<sup>28</sup> 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.<sup>24</sup> The one month and three month limits for pentazocine/naloxone are set as the same based on these significant safety concerns.

Studies of opioid therapy for chronic pain that did not have a nonopioid control group have found that although many patients discontinue opioid therapy for chronic noncancer pain due to adverse effects or insufficient pain relief, there is weak evidence that patients who are able to continue opioid therapy for at least six months can experience clinically significant pain relief and insufficient evidence that function or quality of life improves. These findings suggest that it is very difficult for clinicians to predict whether benefits of opioids for chronic pain will outweigh risks of ongoing treatment for individual patients.<sup>27</sup> Therefore, patients who meet the prior authorization criteria for chronic pain will be approved for 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

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