

QUANTITY LIMIT AND POST LIMIT PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	IMMEDIATE-RELEASE OPIOID ANALGESICS (BRAND AND GENERIC)*
generic name	
dosage form	(codeine sulfate oral solution, tablets)
	(hydromorphone hydrochloride oral liquid, suppositories, tablets)
	(levorphanol tartrate tablets)
	(meperidine hydrochloride oral solution, tablets)
	(morphine sulfate oral soln, oral soln concentrate, suppositories, tablets)
	(oxycodone hydrochloride capsules, oral soln, oral soln concentrate, tabs)
	(oxymorphone hydrochloride tablets)
	(pentazocine/naloxone tablets)
	(tapentadol tablets)
	(tramadol hydrochloride tablets)
Status: CVS Caremark Criteria	
Type: Quantity limit; Post Limit Prior Authorization	

* Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated.

POLICY

FDA-APPROVED INDICATIONS

Codeine Sulfate

Oral Solution

Codeine sulfate is an opioid analgesic indicated for the management of mild to moderately severe pain where the use of an opioid analgesic is appropriate.

Tablets

Codeine sulfate tablets are an opioid analgesic indicated for the relief of mild to moderately severe pain where the use of an opioid analgesic is appropriate.

Hydromorphone Hydrochloride

Oral Liquid, Tablets, Suppositories

Opioids IR - MME Limit and Post Limit Policy 1363-M 01-2017 (2)

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Hydromorphone hydrochloride oral liquid, tablets, and suppositories are indicated for the management of pain in patients where an opioid analgesic is appropriate.

Levorphanol Tartrate

Levorphanol tartrate tablets are indicated for the management of moderate to severe pain where an opioid analgesic is appropriate.

Meperidine Hydrochloride

Oral Solution

Meperidine hydrochloride oral solution is indicated for the relief of moderate to severe pain.

Tablets

Meperidine tablets are indicated for the relief of moderate to severe pain.

Morphine Sulfate

Oral Solution and Oral Concentrate

Morphine sulfate oral solution (10 mg per 5 mL and 20 mg per 5 mL) are formulations of morphine, an opioid agonist, indicated for the relief of moderate to severe acute and chronic pain where use of an opioid analgesic is appropriate.

Morphine sulfate oral solution 100 mg per 5 mL (20 mg/mL) is an opioid analgesic indicated for the relief of moderate to severe acute and chronic pain in opioid-tolerant patients.

Morphine sulfate oral solution 100 mg per 5 mL (20 mg/mL) may cause fatal respiratory depression when administered to patients not previously exposed to opioids. Patients considered to be opioid tolerant are those who are taking at least 60 mg oral morphine per day, or at least 30 mg of oral oxycodone per day, or at least 12 mg hydromorphone per day, or an equianalgesic dose of another opioid, for a week or longer.

Tablets and Suppositories

Morphine sulfate is an opioid agonist indicated for the relief of moderate to severe acute and chronic pain where use of an opioid analgesic is appropriate.

Nucynta (tapentadol)

Nucynta is indicated for the management of moderate to severe acute pain in adults.

Oxycodone Hydrochloride

Capsules

Oxycodone hydrochloride capsule is an opioid analgesic, indicated for the management of moderate to severe acute and chronic pain where use of an opioid analgesic is appropriate.

Oral Solution

Oxycodone hydrochloride Oral Solution 5 mg per 5 mL, is an immediate-release oral formulation of oxycodone hydrochloride indicated for the management of moderate to severe acute and chronic pain where the use of an opioid analgesic is appropriate.

Oxycodone hydrochloride Oral Solution 100 mg per 5 mL (20 mg/mL) is an opioid analgesic indicated for the management of moderate to severe acute and chronic pain in opioid-tolerant patients.

Oxycodone hydrochloride Oral Solution 100 mg per 5 mL (20 mg/mL) may cause fatal respiratory depression when administered to patients not previously exposed to opioids. Patients considered to be opioid tolerant are those who are taking at least 30 mg of oral oxycodone per day, or at least 60 mg oral morphine per day, or at least 12 mg hydromorphone per day, or an equianalgesic dose of another opioid, for a week or longer.

Tablets

Oxycodone hydrochloride tablets are an immediate-release oral formulation of oxycodone hydrochloride indicated for the management of moderate to severe pain where the use of an opioid analgesic is appropriate.

Oxymorphone Hydrochloride

Oxymorphone hydrochloride tablets are indicated for the relief of moderate to severe acute pain where the use of an opioid is appropriate.

Pentazocine/Naloxone

Pentazocine/naloxone is indicated for the relief of moderate to severe pain. Pentazocine/naloxone is indicated for oral use only.

RoxyBond (oxycodone hydrochloride)

RoxyBond 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 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.

Ultram (tramadol)

Ultram is indicated for the management of moderate to moderately severe pain in adults.

PROGRAM DESCRIPTION

Quantity limits do not apply if the patient has a drug in claims history that indicates the patient is being treated for cancer in the past year.

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

INITIAL STEP THERAPY

If the patient has filled a prescription for a ≥ 1-day supply of a drug indicating the patient is being treated for cancer 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 the patient does not meet the initial step therapy criteria, then initial quantity limits will apply. If initial quantities are exceeded, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

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, 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

AND

- The patient has been evaluated and 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 requested drug is being prescribed for moderate to severe ACUTE pain where use of an opioid analgesic is appropriate

Quantity Limit may apply.

Opioid Analgesics IR Quantity Limits Chart

Coverage is provided without prior authorization for 30-day or 90-day IR opioid prescriptions for an amount ≤ 90 MME/day. Coverage for quantities ≤ 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.)

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 oral soln 30 mg/5 mL	15 to 60 mg (2.5 mL to 10 mL) q4h. Max Daily Dose 360 mg.	210 mL*** (27 MME/day)	210 mL*** (27 MME/day)	840 mL*** (54 MME/day)	840 mL*** (54 MME/day)
Codeine sulfate tab 15 mg	15 to 60 mg q4h. Max Daily Dose 360 mg.	42 tabs*** (13.5 MME/day)	42 tabs*** (13.5 MME/day)	84 tabs*** (13.5 MME/day)	84 tabs*** (13.5 MME/day)

Codeine sulfate tab 30 mg	15 to 60 mg q4h. Max Daily Dose 360 mg.	42 tabs*** (27 MME/day)	42 tabs*** (27 MME/day)	84 tabs*** (27 MME/day)	84 tabs*** (27 MME/day)
Codeine sulfate tab 60 mg	15 to 60 mg q4h. Max Daily Dose 360 mg.	42 tabs*** (54 MME/day)	42 tabs*** (54 MME/day)	84 tabs*** (54 MME/day)	84 tabs*** (54 MME/day)
Hydromorphone liquid 1 mg/mL	2.5 mg – 10 mg (2.5 mL to 10 mL) q3-6h	600 mL (80 MME/day)	1800 mL (80 MME/day)	1500 mL (200 MME/day)	4500 mL (200 MME/day)
Hydromorphone supp 3 mg	1 supp q6-8h	120 supps (48 MME/day)	360 supps (48 MME/day)	180 supps (72 MME/day)	540 supps (72 MME/day)
Hydromorphone tab 2 mg	2-4 mg q4-6h	180 tabs (48 MME/day)	540 tabs (48 MME/day)	270 tabs (72 MME/day)	810 tabs (72 MME/day)
Hydromorphone tab 4 mg	2-4 mg q4-6h	150 tabs (80 MME/day)	450 tabs (80 MME/day)	225 tabs (120 MME/day)	675 tabs (120 MME/day)
Hydromorphone tab 8 mg	2-4 mg q4-6h	60 tabs (64 MME/day)	180 tabs (64 MME/day)	90 tabs (96 MME/day)	270 tabs (96 MME/day)
Levorphanol tab 2 mg	2 mg q6-8h	120 tabs (88 MME/day)	360 tabs (88 MME/day)	180 tabs (132 MME/day)	540 tabs (132 MME/day)
Meperidine oral soln 50 mg/5 mL	50-150 mg (5-15 mL) q3-4h	90 mL**** (30 MME/day)	90 mL**** (30 MME/day)	120 mL**** (40 MME/day)	120 mL**** (40 MME/day)
Meperidine tab 50 mg	50-150 mg q3-4h	18 tabs**** (30 MME/day)	18 tabs**** (30 MME/day)	24 tabs**** (40 MME/day)	24 tabs**** (40 MME/day)
Meperidine tab 100 mg	50-150 mg q3-4h	18 tabs**** (60 MME/day)	18 tabs**** (60 MME/day)	24 tabs**** (80 MME/day)	24 tabs**** (80 MME/day)
Morphine sulfate (conc) oral soln 20 mg/mL (100 mg/5 mL)	10-20 mg q4h	135 mL (90 MME/day)	405 mL (90 MME/day)	270 mL (180 MME/day)	810 mL (180 MME/day)
Morphine sulfate oral soln 10 mg/5 mL	10-20 mg q4h	900 mL (60 MME/day)	2700 mL (60 MME/day)	1350 mL (90 MME/day)	4050 mL (90 MME/day)
Morphine sulfate oral soln 20 mg/5 mL	10-20 mg q4h	675 mL (90 MME/day)	2025 mL (90 MME/day)	1350 mL (180 MME/day)	4050 mL (180 MME/day)
Morphine sulfate supp 5 mg	10-20 mg q4h	180 supps (30 MME/day)	540 supps (30 MME/day)	270 supps (45 MME/day)	810 supps (45 MME/day)
Morphine sulfate supp 10 mg	10-20 mg q4h	180 supps (60 MME/day)	540 supps (60 MME/day)	270 supps (90 MME/day)	810 supps (90 MME/day)
Morphine sulfate supp 20 mg	10-20 mg q4h	120 supps (80 MME/day)	360 supps (80 MME/day)	270 supps (180 MME/day)	810 supps (180 MME/day)
Morphine sulfate supp 30 mg	10-20 mg q4h	90 supps (90 MME/day)	270 supps (90 MME/day)	180 supps (180 MME/day)	540 supps (180 MME/day)
Morphine sulfate tab 15 mg	15-30 mg q4h	180 tabs (90 MME/day)	540 tabs (90 MME/day)	270 tabs (135 MME/day)	810 tabs (135 MME/day)
Morphine sulfate tab 30 mg	15-30 mg q4h	90 tabs (90 MME/day)	270 tabs (90 MME/day)	180 tabs (180 MME/day)	540 tabs (180 MME/day)
Oxycodone cap 5 mg	5-15 mg q4-6h	180 caps (45 MME/day)	540 caps (45 MME/day)	270 caps (67.5 MME/day)	810 caps (67.5 MME/day)
Oxycodone oral concentrate 100 mg/5 mL (20 mg/mL)	5-15 mg q4-6h	90 mL (90 MME/day)	270 mL (90 MME/day)	180 mL (180 MME/day)	540 mL (180 MME/day)
Oxycodone soln 5 mg/5 mL	5-15 mg q4-6h	900 mL (45 MME/day)	2700 mL (45 MME/day)	2700 mL (135 MME/day)	8100 mL (135 MME/day)
Oxaydo 5 mg	5-15 mg every 4-6h	180 tabs (45 MME/day)	540 tabs (45 MME/day)	270 tabs (67.5 MME/day)	810 tabs (67.5 MME/day)
Oxaydo 7.5 mg	5-15 mg every 4-6h	180 tabs (67.5 MME/day)	540 tabs (67.5 MME/day)	270 tabs (101.25 MME/day)	810 tabs (101.25 MME/day)
Oxycodone tab 5 mg	5-15 mg q4-6h	180 tabs (45 MME/day)	540 tabs (45 MME/day)	270 tabs (67.5 MME/day)	810 tabs (67.5 MME/day)
Oxycodone tab 10 mg	5-15 mg q4-6h	180 tabs (90 MME/day)	540 tabs (90 MME/day)	270 tabs (135 MME/day)	810 tabs (135 MME/day)
Oxycodone tab 15 mg	5-15 mg q4-6h	120 tabs (90 MME/day)	360 tabs (90 MME/day)	180 tabs (135 MME/day)	540 tabs (135 MME/day)
Oxycodone tab 20 mg	5-15 mg q4-6h	90 tabs (90 MME/day)	270 tabs (90 MME/day)	180 tabs (180 MME/day)	540 tabs (180 MME/day)
Oxycodone tab 30 mg	5-15 mg q4-6h	60 tabs (90 MME/day)	180 tabs (90 MME/day)	120 tabs (180 MME/day)	360 tabs (180 MME/day)
Oxymorphone tab 5 mg	10-20 mg q4-6h	180 tabs	540 tabs	360 tabs	1080 tabs

		(90 MME/day)	(90 MME/day)	(180 MME/day)	(180 MME/day)
Oxymorphone tab 10 mg	10-20 mg q4-6h	90 tabs (90 MME/day)	270 tabs (90 MME/day)	180 tabs (180 MME/day)	540 tabs (180 MME/day)
Pentazocine/naloxone 50/0.5 mg	1 tab q3-4h. Total daily dose should not exceed 12 tablets.	120 tabs*** (74 MME/day)	120 tabs*** (74 MME/day)	300 tabs*** (185 MME/day)	300 tabs*** (185 MME/day)
RoxyBond 5 mg	5-15 mg q4-6h	180 tabs (45 MME/day)	540 tabs (45 MME/day)	270 tabs (67.5 MME/day)	810 tabs (67.5 MME/day)
RoxyBond 15 mg	5-15 mg q4-6h	120 tabs (90 MME/day)	360 tabs (90 MME/day)	180 tabs (135 MME/day)	540 tabs (135 MME/day)
RoxyBond 30 mg	5-15 mg q4-6h	60 tabs (90 MME/day)	180 tabs (90 MME/day)	120 tabs (180 MME/day)	360 tabs (180 MME/day)
Tapentadol 50 mg	50 mg, 75 mg, or 100 mg every 4 to 6 hours. Max daily dose is 700 mg on the first day and 600 mg on subsequent days.	120 tabs (80 MME/day)	360 tabs (80 MME/day)	240 tabs (160 MME/day)	720 tabs (160 MME/day)
Tapentadol 75 mg	50 mg, 75 mg, or 100 mg every 4 to 6 hours. Max daily dose is 700 mg on the first day and 600 mg on subsequent days.	90 tabs (90 MME/day)	270 tabs (90 MME/day)	180 tabs (180 MME/day)	540 tabs (180 MME/day)
Tapentadol 100 mg	50 mg, 75 mg, or 100 mg every 4 to 6 hours. Max daily dose is 700 mg on the first day and 600 mg on subsequent days.	60 tabs (80 MME/day)	180 tabs (80 MME/day)	120 tabs (160 MME/day)	360 tabs (160 MME/day)
Tramadol 50 mg	50-100 mg q4-6h, MAX = 400 mg/day	180 tabs (30 MME/day)	540 tabs (30 MME/day)	240 tabs (40 MME/day)	720 tabs (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.

**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.

****Due to risk of accumulation, the 30-day and 90-day initial limit allows a 3-day supply only and the 30-day and 90-day post limit allows a 4-day supply only.

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