

Reference number(s)
2221-M

Duration Limit; Initial Limit; Post Limit Prior Authorization Immediate-Release Opioid Analgesics 7-Day Acute Pain Duration Limit with Morphine Milligram Equivalent (MME) Limit and Post Limit

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
All brands	codeine sulfate	tablets
All brands	hydromorphone hydrochloride	oral solution, suppositories, tablets
All brands	levorphanol tartrate	tablets
All brands	mepiperidine hydrochloride	oral solution, tablets
All brands	morphine sulfate	oral solution, oral solution concentrate, suppositories, tablets
All brands	oxycodone hydrochloride	capsules, oral solution, oral solution concentrate, tablets
All brands	oxymorphone hydrochloride	tablets
All brands	pentazocine/naloxone	tablets
All brands	tapentadol	tablets
All brands	tramadol hydrochloride	oral solution, tablets

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Indications

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, which can occur at any dosage or duration, 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.

Codeine Sulfate Tablets should not be used for an extended period of time unless the pain remains severe enough to require an opioid analgesic and for which alternative treatment options continue to be inadequate.

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 and for which alternative treatments are inadequate.

Limitations of Use

Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, 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

Dilaudid (hydromorphone hydrochloride) Oral Solution and Dilaudid (hydromorphone hydrochloride) Tablets should not be used for an extended period of time unless the pain remains severe enough to require an opioid analgesic and for which alternative treatment options continue to be inadequate.

Hydromorphone Hydrochloride

Hydromorphone Hydrochloride Suppositories 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 Suppositories 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.

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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, which can occur at any dosage or duration, reserve Levorphanol Tartrate 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.

Levorphanol Tartrate Tablets should not be used for an extended period of time unless the pain remains severe enough to require an opioid analgesic for which alternative treatment options continue to be inadequate.

Meperidine Hydrochloride

Meperidine Hydrochloride Tablets and Oral Solution 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, which can occur at any dosage or duration, reserve Meperidine Hydrochloride Tablets and Oral Solution 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 Tablets or Oral Solution should not be used for an extended period of time unless the pain remains severe enough to require an opioid analgesic and for which alternative treatment options continue to be inadequate.

Meperidine Hydrochloride Tablets or Oral Solution should not be used for treatment of chronic pain. Use of Meperidine Hydrochloride Tablets or Oral Solution for an extended period of time 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 2 mg/mL and 4 mg/mL 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 adult 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.

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Tablets

Morphine Sulfate Tablets are indicated for the management of:

- adult and pediatric patients weighing at least 50 kg and above 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, which can occur at any dosage or duration, reserve Morphine Sulfate 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.

Morphine Sulfate Oral Solution and Tablets should not be used for an extended period of time unless the pain remains severe enough to require an opioid analgesic and for which alternative treatment options continue to be inadequate.

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 and pediatric patients aged 6 years and older with a body weight of at least 40 kg.

Limitations of Use

Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dose or duration, reserve Nucynta (tapentadol) 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.

Nucynta (tapentadol) tablets should not be used for an extended period of time unless the pain remains severe enough to require an opioid analgesic and for which alternative treatment options continue to be inadequate.

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, which can occur at any dosage or duration, 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.

Oxaydo should not be used for an extended period of time unless the pain remains severe enough to require an opioid analgesic and for which alternative treatment options continue to be inadequate.

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Oxycodone Hydrochloride

Capsules

Oxycodone Hydrochloride (HCl) Capsules are an opioid agonist indicated in adults 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 adults.

Tablets

Oxycodone Hydrochloride (HCl) 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, which can occur at any dosage or duration, 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.

Oxycodone Hydrochloride Capsules should not be used for an extended period of time unless the pain remains severe enough to require an opioid analgesic and for which alternative treatment options continue to be inadequate.

Oxymorphone Hydrochloride

Oxymorphone Hydrochloride Tablets are an opioid agonist 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, which can occur at any dosage or duration, 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

Oxymorphone Hydrochloride Tablets should not be used for an extended period of time unless the pain remains severe enough to require an opioid analgesic and for which alternative treatment options continue to be inadequate.

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.

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Limitations of Use

Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, 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.

Pentazocine and Naloxone Tablets should not be used for an extended period of time unless the pain remains severe enough to require an opioid analgesic and for which alternative treatment options continue to be inadequate.

Qdolo (tramadol hydrochloride)

Qdolo (tramadol hydrochloride) 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, which can occur at any dosage or duration, reserve Qdolo (tramadol hydrochloride) 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) should not be used for an extended period of time unless the pain remains severe enough to require an opioid analgesic and for which alternative treatment options continue to be inadequate.

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, which can occur at any dosage or duration, 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.

RoxyBond (oxycodone hydrochloride) should not be used for an extended period of time unless the pain remains severe enough to require an opioid analgesic and for which alternative treatment options continue to be inadequate.

Tramadol Hydrochloride Tablets, Oral Solution

Tramadol Hydrochloride Tablets, USP and Tramadol 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.

Limitations of Use

Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve tramadol hydrochloride tablets and Tramadol Hydrochloride Oral Solution 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,

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- Have not provided adequate analgesia or are not expected to provide adequate analgesia.

Ultram (tramadol hydrochloride)

Ultram (tramadol hydrochloride) 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 tramadol hydrochloride tablets and Tramadol Hydrochloride Oral Solution 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.

Screen out 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). A prior authorization (PA) may be submitted for additional quantities. The prior authorization criteria would then be applied to requests

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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.

Limit Criteria

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

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. 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 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.

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Coverage Criteria

[NOTE: These drugs should be prescribed only by health care professionals who are knowledgeable about the use of opioids and how to mitigate the associated risks.]

Pain associated with Cancer, Sickle Cell Disease, a Terminal Condition, or Pain being Managed through Hospice or Palliative Care

Authorization may be granted when 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

Acute Pain

Authorization may be granted when the patient requires treatment for ACUTE pain severe enough to require an opioid analgesic when ALL of the following criteria are met:

[NOTE: Many acute pain conditions (e.g., the pain that occurs with a number of surgical procedures or acute musculoskeletal injuries) require no more than a few days of an opioid analgesic.]

- The patient can safely take the requested dose based on their history of opioid use [NOTE: The lowest dosage necessary to achieve adequate analgesia should be prescribed.]
- The patient has been evaluated and the patient will be monitored regularly for the development of opioid use disorder

Chronic Pain

Authorization may be granted when the requested drug is being prescribed for CHRONIC pain severe enough to require an opioid analgesic when ALL of the following criteria are met:

[NOTE: Chronic pain is generally defined as pain that typically lasts greater than 3 months.]

- The patient can safely take the requested dose based on their history of opioid use [NOTE: The lowest dosage necessary to achieve adequate analgesia should be prescribed.]
- The patient has been evaluated and the patient will be monitored regularly for the development of opioid use disorder
- 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 [NOTE: Because the risk of overdose increases as opioid doses increase, reserve titration to higher doses for patients in whom lower doses are insufficiently effective and in whom the expected benefits of using a higher dose opioid clearly outweigh the substantial risks.]

Quantity Limits May Apply

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 morphine milligram equivalent (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).

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.

For drugs that list “Does Not Apply” in column B, the 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; there should be no 3 month supplies filled.

For meperidine products, 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.

For codeine products, the initial quantity limit 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.

Drug/Strength	Labeled Dosing	COLUMN A Initial 1 Month Limit ≤ 90 MME/day (per 25 days)	COLUMN B Initial 3 Month Limit ≤ 90 MME/day (per 75 days)	COLUMN C Post 1 Month Limit ≤ 200 MME/day (per 25 days)	COLUMN D Post 3 Month Limit ≤ 200 MME/day (per 75 days)
Codeine sulfate tablets 15 mg	once every 4 hours, Max Daily Dose 360 mg.	42 tablets/month 6 tablets/day (13.5 MME/day)	Does Not Apply	84 tablets/month 6 tablets/day (13.5 MME/day)	Use Column C
Codeine sulfate tablets 30 mg	once every 4 hours, Max Daily Dose 360 mg.	42 tablets/month 6 tablets/day (27 MME/day)	Does Not Apply	84 tablets/month 6 tablets/day (27 MME/day)	Use Column C
Codeine sulfate tablets 60 mg	once every 4 hours, Max Daily Dose 360 mg.	42 tablets/month 6 tablets/day (54 MME/day)	Does Not Apply	84 tablets/month 6 tablets/day (54 MME/day)	Use Column C
Hydromorphone oral solution 5 mg/5 mL (1 mg/mL)	once every 3 to 6 hours	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)

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Drug/Strength	Labeled Dosing	COLUMN A Initial 1 Month Limit ≤ 90 MME/day (per 25 days)	COLUMN B Initial 3 Month Limit ≤ 90 MME/day (per 75 days)	COLUMN C Post 1 Month Limit ≤ 200 MME/day (per 25 days)	COLUMN D Post 3 Month Limit ≤ 200 MME/day (per 75 days)
Hydromorphone suppositories 3 mg	once every 6 to 8 hours	120 suppositories/month 4 suppositories/day (60 MME/day)	360 suppositories/3 months 4 suppositories/day (60 MME/day)	180 suppositories/month 6 suppositories/day (90 MME/day)	540 suppositories/3 months 6 suppositories/day (90 MME/day)
Hydromorphone tablets 2 mg	once every 4 to 6 hours	180 tablets/month 6 tablets/day (60 MME/day)	540 tablets/3 months 6 tablets/day (60 MME/day)	270 tablets/month 9 tablets/day (90 MME/day)	810 tablets/3 months 9 tablets/day (90 MME/day)
Hydromorphone tablets 4 mg	once every 4 to 6 hours	120 tablets/month 4 tablets/day (80 MME/day)	360 tablets/3 months 4 tablets/day (80 MME/day)	180 tablets/month 6 tablets/day (120 MME/day)	540 tablets/3 months 6 tablets/day (120 MME/day)
Hydromorphone tablets 8 mg	once every 4 to 6 hours	60 tablets/month 2 tablets/day (80 MME/day)	180 tablets/3 months 2 tablets/day (80 MME/day)	90 tablets/month 3 tablets/day (120 MME/day)	270 tablets/3 months 3 tablets/day (120 MME/day)
Levorphanol tablets 1 mg	once every 6 to 8 hours	120 tablets/month 4 tablets/day (44 MME/day)	360 tablets/3 months 4 tablets/day (44 MME/day)	180 tablets/month 6 tablets/day (66 MME/day)	540 tablets/3 months 6 tablets/day (66 MME/day)
Levorphanol tablets 2 mg	once every 6 to 8 hours	120 tablets/month 4 tablets/day (88 MME/day)	360 tablets/3 months 4 tablets/day (88 MME/day)	180 tablets/month 6 tablets/day (132 MME/day)	540 tablets/3 months 6 tablets/day (132 MME/day)
Levorphanol tablets 3 mg	once every 6 to 8 hours	60 tablets/month 2 tablets/day (66 MME/day)	180 tablets/3 months 2 tablets/day (66 MME/day)	180 tablets/month 6 tablets/day (198 MME/day)	540 tablets/3 months 6 tablets/day (198 MME/day)
Meperidine oral solution 50 mg/5 mL	once every 3 to 4 hours	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 tablets 50 mg	once every 3 to 4 hours	18 tablets/month 6 tablets/day (30 MME/day)	Does Not Apply	24 tablets/month 6 tablets/day (30 MME/day)	Use Column C
Morphine sulfate (concentrate) oral	once every 4 hours	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)

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solution 20 mg/mL (100 mg/5 mL)					
Morphine sulfate oral solution 10 mg/5 mL	once every 4 hours	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 solution 20 mg/5 mL	once every 4 hours	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 suppositories 5 mg	once every 4 hours	180 suppositories/mon th 6 suppositories/day (30 MME/day)	540 suppositories/3 month 6 suppositories/day (30 MME/day)	270 suppositories/mon th 9 suppositories/day (45 MME/day)	810 suppositories/3 months 9 suppositories/day (45 MME/day)
Morphine sulfate suppositories 10 mg	once every 4 hours	180 suppositories/mon th 6 suppositories/day (60 MME/day)	540 suppositories/3 month 6 suppositories/day (60 MME/day)	270 suppositories/mon th 9 suppositories/day (90 MME/day)	810 suppositories/3 months 9 suppositories/day (90 MME/day)
Morphine sulfate suppositories 20 mg	once every 4 hours	120 suppositories/mon th 4 suppositories/day (80 MME/day)	360 suppositories/3 months 4 suppositories/day (80 MME/day)	270 suppositories/mon th 9 suppositories/day (180 MME/day)	810 suppositories/3 months 9 suppositories/day (180 MME/day)
Morphine sulfate suppositories 30 mg	once every 4 hours	90 suppositories/mon th 3 suppositories/day (90 MME/day)	270 suppositories/3 months 3 suppositories/day (90 MME/day)	180 suppositories/mon th 6 suppositories/day (180 MME/day)	540 suppositories/3 months 6 suppositories/day (180 MME/day)
Morphine sulfate tablets 15 mg	once every 4 hours	180 tablets/month 6 tablets/day (90 MME/day)	540 tablets/3 months 6 tablets/day (90 MME/day)	270 tablets/month 9 tablets/day (135 MME/day)	810 tablets/3 months 9 tablets/day (135 MME/day)
Morphine sulfate tablets 30 mg	once every 4 hours	90 tablets/month 3 tablets/day (90 MME/day)	270 tablets/3 months 3 tablets/day	180 tablets/month 6 tablets/day (180 MME/day)	540 tablets/3 months 6 tablets/day

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Drug/Strength	Labeled Dosing	COLUMN A Initial 1 Month Limit ≤ 90 MME/day (per 25 days)	COLUMN B Initial 3 Month Limit ≤ 90 MME/day (per 75 days)	COLUMN C Post 1 Month Limit ≤ 200 MME/day (per 25 days)	COLUMN D Post 3 Month Limit ≤ 200 MME/day (per 75 days)
			(90 MME/day)		(180 MME/day)
Oxycodone capsules 5 mg	once every 4 to 6 hours	180 capsules/month 6 capsules/day (45 MME/day)	540 capsules/3 months 6 capsules/day (45 MME/day)	270 capsules/month 9 capsules/day (67.5 MME/day)	810 capsules/3 months 9 capsules/day (67.5 MME/day)
Oxycodone oral concentrate 100 mg/5 mL (20 mg/mL)	once every 4 to 6 hours	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 solution 5 mg/5 mL	once every 4 to 6 hours	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 tablets 5 mg	once every 4 to 6 hours	180 tablets/month 6 tablets/day (45 MME/day)	540 tablets/3 months 6 tablets/day (45 MME/day)	270 tablets/month 9 tablets/day (67.5 MME/day)	810 tablets/3 months 9 tablets/day (67.5 MME/day)
Oxycodone (Oxaydo) tablets 5 mg	once every 4 to 6 hours	180 tablets/month 6 tablets/day (45 MME/day)	540 tablets/3 months 6 tablets/day (45 MME/day)	270 tablets/month 9 tablets/day (67.5 MME/day)	810 tablets/3 months 9 tablets/day (67.5 MME/day)
Oxycodone (RoxyBond) tablets 5 mg	once every 4 to 6 hours	180 tablets/month 6 tablets/day (45 MME/day)	540 tablets/3 months 6 tablets/day (45 MME/day)	270 tablets/month 9 tablets/day (67.5 MME/day)	810 tablets/3 months 9 tablets/day (67.5 MME/day)
Oxycodone (Oxaydo) tablets 7.5 mg	once every 4 to 6 hours	180 tablets/month 6 tablets/day (67.5 MME/day)	540 tablets/3 months 6 tablets/day (67.5 MME/day)	270 tablets/month 9 tablets/day (101.25 MME/day)	810 tablets/3 months 9 tablets/day (101.25 MME/day)
Oxycodone tablets 10 mg	once every 4 to 6 hours	180 tablets/month 6 tablets/day (90 MME/day)	540 tablets/3 months 6 tablets/day (90 MME/day)	270 tablets/month 9 tablets/day (135 MME/day)	810 tablets/3 months 9 tablets/day (135 MME/day)
Oxycodone (RoxyBond) tablets 10 mg	once every 4 to 6 hours	180 tablets/month 6 tablets/day (90 MME/day)	540 tablets/3 months 6 tablets/day (90 MME/day)	270 tablets/month 9 tablets/day (135 MME/day)	810 tablets/3 months 9 tablets/day (135 MME/day)
Oxycodone tablets 15 mg	once every 4 to 6 hours	120 tablets/month 4 tablets/day (90 MME/day)	360 tablets/3 months 4 tablets/day	180 tablets/month 6 tablets/day (135 MME/day)	540 tablets/3 months 6 tablets/day

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Drug/Strength	Labeled Dosing	COLUMN A Initial 1 Month Limit ≤ 90 MME/day (per 25 days)	COLUMN B Initial 3 Month Limit ≤ 90 MME/day (per 75 days)	COLUMN C Post 1 Month Limit ≤ 200 MME/day (per 25 days)	COLUMN D Post 3 Month Limit ≤ 200 MME/day (per 75 days)
			(90 MME/day)		(135 MME/day)
Oxycodone (RoxyBond) tablets 15 mg	once every 4 to 6 hours	120 tablets/month 4 tablets/day (90 MME/day)	360 tablets/3 months 4 tablets/day (90 MME/day)	180 tablets/month 6 tablets/day (135 MME/day)	540 tablets/3 months 6 tablets/day (135 MME/day)
Oxycodone tablets 20 mg	once every 4 to 6 hours	90 tablets/month 3 tablets/day (90 MME/day)	270 tablets/3 months 3 tablets/day (90 MME/day)	180 tablets/month 6 tablets/day (180 MME/day)	540 tablets/3 months 6 tablets/day (180 MME/day)
Oxycodone tablets 30 mg	once every 4 to 6 hours	60 tablets/month 2 tablets/day (90 MME/day)	180 tablets/3 months 2 tablets/day (90 MME/day)	120 tablets/month 4 tablets/day (180 MME/day)	360 tablets/3 months 4 tablets/day (180 MME/day)
Oxycodone (RoxyBond) tablets 30 mg	once every 4 to 6 hours	60 tablets/month 2 tablets/day (90 MME/day)	180 tablets/3 months 2 tablets/day (90 MME/day)	120 tablets/month 4 tablets/day (180 MME/day)	360 tablets/3 months 4 tablets/day (180 MME/day)
Oxymorphone tablets 5 mg	once every 4 to 6 hours	180 tablets/month 6 tablets/day (90 MME/day)	540 tablets/3 months 6 tablets/day (90 MME/day)	360 tablets/month 12 tablets/day (180 MME/day)	1080 tablets/3 months 12 tablets/day (180 MME/day)
Oxymorphone tablets 10 mg	once every 4 to 6 hours	90 tablets/month 3 tablets/day (90 MME/day)	270 tablets/3 months 3 tablets/day (90 MME/day)	180 tablets/month 6 tablets/day (180 MME/day)	540 tablets/3 months 6 tablets/day (180 MME/day)
Pentazocine/naloxone 50/0.5 mg	once every 3 to 4 hours, Total daily dose should not exceed 12 tablets.	120 tablets/month 4 tablets/day (74 MME/day)	Does Not Apply	300 tablets/month 10 tablets/day (185 MME/day)	Use Column C
Tapentadol (Nucynta) tablets 50 mg	once every 4 to 6 hours, Max daily dose is 700 mg on the first day and 600 mg on subsequent days.	120 tablets/month 4 tablets/day (80 MME/day)	360 tablets/3 months 4 tablets/day (80 MME/day)	240 tablets/month 8 tablets/day (160 MME/day)	720 tablets/3 months 8 tablets/day (160 MME/day)
Tapentadol (Nucynta) tablets 75 mg	once every 4 to 6 hours, Max daily dose is 700 mg on the first day and	90 tablets/month 3 tablets/day (90 MME/day)	270 tablets/3 months 3 tablets/day (90 MME/day)	180 tablets/month 6 tablets/day (180 MME/day)	540 tablets/3 months 6 tablets/day (180 MME/day)

Reference number(s)
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Drug/Strength	Labeled Dosing	COLUMN A Initial 1 Month Limit ≤ 90 MME/day (per 25 days)	COLUMN B Initial 3 Month Limit ≤ 90 MME/day (per 75 days)	COLUMN C Post 1 Month Limit ≤ 200 MME/day (per 25 days)	COLUMN D Post 3 Month Limit ≤ 200 MME/day (per 75 days)
	600 mg on subsequent days.				
Tapentadol (Nucynta) tablets 100 mg	once every 4 to 6 hours, Max daily dose is 700 mg on the first day and 600 mg on subsequent days.	60 tablets/month 2 tablets/day (80 MME/day)	180 tablets/3 months 2 tablets/day (80 MME/day)	120 tablets/month 4 tablets/day (160 MME/day)	360 tablets/3 months 4 tablets/day (160 MME/day)
Tramadol oral solution 5 mg/mL	once every 4 to 6 hours, 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 solution 5 mg/mL	once every 4 to 6 hours, 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 25 mg	once every 4 to 6 hours, Max Daily Dose 400 mg.	120 tablets/month 4 tablets/day (20 MME/day)	360 tablets/3 months 4 tablets/day (20 MME/day)	180 tablets/month 6 tablets/day (30 MME/day)	540 tablets/3 months 6 tablets/day (30 MME/day)
Tramadol 50 mg	once every 4 to 6 hours, Max Daily Dose 400 mg.	180 tablets/month 6 tablets/day (60 MME/day)	540 tablets/3 months 6 tablets/day (60 MME/day)	240 tablets/month 8 tablets/day (80 MME/day)	720 tablets/3 months 8 tablets/day (80 MME/day)
Tramadol 100 mg	once every 4 to 6 hours, Max Daily Dose 400 mg.	90 tablets/month 3 tablets/day (60 MME/day)	270 tablets/3 months 3 tablets/day (60 MME/day)	120 tablets/month 4 tablets/day (80 MME/day)	360 tablets/3 months 4 tablets/day (80 MME/day)

Duration of Approval (DOA)

- 2221-M:
 - Pain associated with cancer, sickle cell disease, a terminal condition, or pain being managed through hospice or palliative care: DOA: 12 months
 - Chronic pain: DOA: 6 months
 - Acute pain: DOA: 1 month

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References

- Codeine Sulfate Tablets [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; December 2023.
- Dilaudid oral solution, tablets [package insert]. Stamford, CT: Purdue Pharma L.P.; December 2023.
- Hydromorphone HCl suppositories [package insert]. Minneapolis, MN: Perrigo; November 2020.
- Levorphanol Tartrate [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; October 2023.
- Meperidine Hydrochloride oral solution, tablets [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; September 2023.
- Morphine Sulfate 10 mg/5 mL, 20 mg/5 mL, 100 mg/5 mL (20 mg/mL) oral solution [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; December 2023.
- Morphine Sulfate suppositories [package insert]. Minneapolis, MN: Perrigo; March 2019.
- Morphine Sulfate tablets [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; December 2023.
- Nucynta tablets [package insert]. Stoughton, MA: Collegium Pharmaceutical, Inc.; July 2023.
- Oxaydo [package insert]. Lake Forest, IL: Zyla Life Sciences US LLC.; December 2023.
- Oxycodone Hydrochloride tablets [package insert]. Brookhaven, NY: Amneal Pharmaceuticals of NY, LLC; December 2021.
- Oxycodone Hydrochloride capsules [package insert]. Allentown, PA: Genus Lifesciences Inc.; December 2023.
- Oxycodone Hydrochloride 5 mg/5 mL, 100 mg/5 mL (20 mg/mL) oral solution [package insert]. Webster Groves, MO: SpecGx LLC; November 2022.
- Oxymorphone [package insert]. Laurelton, NY: Epic Pharma, LLC; December 2023.
- Pentazocine and Naloxone [package insert]. Somerset, NJ: Novel Laboratories, Inc; December 2023.
- Qdolo [package insert]. Athens, GA: Athena Bioscience, LLC; December 2023.
- RoxyBond [package insert]. Princeton, NJ: Protega Pharmaceuticals Inc., LLC; May 2024.
- Tramadol [package insert]. Plainsboro, NJ: Advagen Pharma Ltd.; August 2023.
- Tramadol Oral Solution [package insert]. Tampa FL: TruPharma, LLC; November 2022.
- Ultram [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; September 2021.
- Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. <https://online.lexi.com>. Accessed November 7, 2023.
- Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2023. <https://online.lexi.com>. Accessed November 7, 2023.
- Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 11/07/2023).
- Palliative Care. NCCN Guidelines version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/palliative.pdf. Accessed November 7, 2023.
- Adult Cancer Pain. NCCN Guidelines version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/pain.pdf. Accessed November 7, 2023.
- Chou R, Fanciullo G, Fine P, et al. Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain. *The Journal of Pain*. 2009;10:113-130.
- Dowell D, Ragan, KR, Jones, CM, et al; CDC Clinical Practice Guideline for Prescribing Opioids for Pain – United States, 2022. *MMWR Recomm Rep*. 2022;71:1–95. Available at: <http://dx.doi.org/10.15585/mmwr.rr7103a1>. Accessed November 7, 2023.
- Clinical Pharmacology [database online]. Tampa, FL: Elsevier/Gold Standard; <https://www.clinicalkey.com/pharmacology/> [available with subscription]. Accessed November 7, 2023.

Reference number(s)
2221-M

29. National Heart, Lung, and Blood Institute. Evidence-Based Management of Sickle Cell Disease: Expert Panel Report, 2014. Available at: https://www.nhlbi.nih.gov/sites/default/files/media/docs/sickle-cell-disease-report%20020816_0.pdf. Accessed November 7, 2023.
30. U.S. Food & Drug Administration. FDA updates prescribing information for all opioid pain medicines to provide additional guidance for safe use. April 13, 2023. Available at: <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-prescribing-information-all-opioid-pain-medicines-provide-additional-guidance-safe-use>. Accessed January 4, 2024.