

# Initial Step Therapy; Initial Limit; Post Limit Prior Authorization Extended-Release Opioid Analgesics Step Therapy with Morphine Milliequivalent (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
Belbuca	buprenorphine	buccal film
Butrans	buprenorphine	transdermal system
ConZip	tramadol hydrochloride extended-release	capsules
fentanyl (all brands)	fentanyl	transdermal system
hydrocodone bitartrate extended-release (generic Zohydro ER – brand unavailable)	hydrocodone bitartrate extended-release	capsules
hydromorphone hydrochloride extended-release (generic Exalgo – brand unavailable)	hydromorphone hydrochloride extended-release	tablets

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Brand Name	Generic Name	Dosage Form
Hysingla ER	hydrocodone bitartrate extended-release	tablets
methadone 5 mg, 10 mg (all brands)	methadone hydrochloride	tablets
Methadone 200 mg/20 mL	methadone hydrochloride	injection
Methadone Intensol 10 mg/mL	methadone hydrochloride	oral concentrate
methadone 5 mg/5 mL & 10 mg/5 mL (all brands)	methadone hydrochloride	oral solution
morphine extended-release (generic Avinza – brand unavailable)	morphine extended-release	capsules
morphine extended-release (generic Kadian – brand unavailable)	morphine extended-release	capsules
MS Contin	morphine extended-release	tablets
Nucynta ER	tapentadol extended-release	tablets
OxyContin	oxycodone hydrochloride extended-release	tablets
oxymorphone hydrochloride extended-release (generic Opana ER – brand unavailable)	oxymorphone hydrochloride extended-release	tablets
tramadol hydrochloride extended-release (generic Ryzolt – brand unavailable)	tramadol hydrochloride extended-release	tablets
tramadol hydrochloride extended-release (generic Ultram ER – brand unavailable)	tramadol hydrochloride extended-release	tablets
Xtampza ER	oxycodone extended-release	capsules

# Indications

## FDA-approved Indications

### Belbuca, Butrans (buprenorphine)

Belbuca, Butrans are indicated for the management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate.

#### Limitations of Use

- Because of the risks of addiction, abuse and misuse with opioids, which can occur at any dosage or duration, and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve Belbuca, Butrans for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Belbuca, Butrans are not indicated as an as-needed (prn) analgesic.

### ConZip (tramadol hydrochloride extended-release)

ConZip is indicated for the management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate.

#### Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve ConZip use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- ConZip is not indicated as an as-needed (prn) analgesic.

### Fentanyl Transdermal System

Fentanyl transdermal system is indicated for the management of severe and persistent pain in opioid tolerant patients, that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate.

Patients considered opioid-tolerant are those who are taking, for one week or longer, at least 60 mg morphine per day, 25 mcg transdermal fentanyl per hour, 30 mg oral oxycodone per day, 8 mg oral hydromorphone per day, 25 mg oral oxymorphone per day, 60 mg oral hydrocodone per day, or an equianalgesic dose of another opioid.

#### Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve fentanyl transdermal system for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-

release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.

- Fentanyl transdermal system is not indicated as an as-needed (prn) analgesic.

## Hydrocodone Bitartrate Extended-Release

Hydrocodone bitartrate extended-release capsules are indicated for the management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate.

### Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve hydrocodone bitartrate extended-release capsules for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Hydrocodone bitartrate extended-release capsules are not indicated as an as-needed (prn) analgesic.

## Hydromorphone Hydrochloride Extended-Release

Hydromorphone hydrochloride extended-release tablets are indicated for the management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate.

Patients considered opioid tolerant are those who are receiving, for one week or longer, at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl per hour, 30 mg oral oxycodone per day, 8 mg oral hydromorphone per day, 25 mg oral oxymorphone per day, 60 mg oral hydrocodone per day, or an equianalgesic dose of another opioid.

### Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve hydromorphone hydrochloride extended-release tablets for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Hydromorphone hydrochloride extended-release tablets are not indicated as an as-needed (prn) analgesic.

## Hysingla ER (hydrocodone bitartrate extended-release)

Hysingla ER is indicated for the management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate.

## Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve Hysingla ER for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Hysingla ER is not indicated as an as-needed (prn) analgesic.

## Methadone Hydrochloride Injection

Methadone Hydrochloride Injection is indicated for the management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate.

### Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve Methadone Hydrochloride Injection for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Methadone Hydrochloride Injection is not indicated as an as-needed (prn) analgesic.

For use in temporary treatment of opioid dependence in patients unable to take oral medication.

### Limitations of Use

- Injectable methadone products are not approved for the outpatient treatment of opioid dependence. In this patient population, parenteral methadone is to be used only for patients unable to take oral medication, such as hospitalized patients.

## Methadone Intensol

Methadone Hydrochloride oral concentrate (Intensol) contains methadone, an opioid agonist indicated for the:

- Management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

### Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with long-acting opioids, reserve Methadone Hydrochloride Intensol for use in patients for whom alternative analgesic treatment options (e.g., non-opioid analgesics or immediate-release opioid analgesics) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Methadone Hydrochloride Intensol is not indicated as an as-needed (prn) analgesic.
- Detoxification treatment of opioid addiction (heroin or other morphine-like drugs).

- Maintenance treatment of opioid addiction (heroin or other morphine-like drugs), in conjunction with appropriate social and medical services.

#### **Limitations of Use**

- Methadone products used for the treatment of opioid addiction in detoxification or maintenance programs are subject to the conditions for distribution and use required under 21 CFR, Title 42, Sec. 8.

### **Methadone Oral Solution**

Methadone hydrochloride oral solution is indicated for the:

- Management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options 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 methadone hydrochloride oral solution for use in patients for whom alternative analgesic treatment options (e.g., non-opioid analgesics or opioid combination products) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Methadone hydrochloride oral solution is not indicated as an as-needed (prn) analgesic.
- Detoxification treatment of opioid addiction (heroin or other morphine-like drugs).
- Maintenance treatment of opioid addiction (heroin or other morphine-like drugs), in conjunction with appropriate social and medical services.

#### **Limitations of Use**

- Methadone products used for the treatment of opioid addiction in detoxification or maintenance programs are subject to the conditions for distribution and use required under 42 CFR 8.12.

### **Methadone Tablets**

Methadone hydrochloride tablets are indicated for the:

- Management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options 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 methadone hydrochloride tablets for use in patients for whom alternative analgesic treatment options (e.g., non-opioid analgesics or immediate-release opioid analgesics) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Methadone hydrochloride tablets are not indicated as an as-needed (prn) analgesic.
- Detoxification treatment of opioid addiction (heroin or other morphine-like drugs).
- Maintenance treatment of opioid addiction (heroin or other morphine-like drugs), in conjunction with appropriate social and medical services.

## Limitations of Use

- Methadone products used for the treatment of opioid addiction in detoxification or maintenance programs are subject to the conditions for distribution and use required under 42 CFR 8.12.

## Conditions For Distribution And Use Of Methadone Products For The Treatment Of Opioid Addiction

### Code of Federal Regulations, Title 42, Sec 8

Methadone products when used for the treatment of opioid addiction in detoxification or maintenance programs, shall be dispensed only by opioid treatment programs (and agencies, practitioners or institutions by formal agreement with the program sponsor) certified by the Substance Abuse and Mental Health Services Administration and approved by the designated state authority. Certified treatment programs shall dispense and use methadone in oral form only and according to the treatment requirements stipulated in the Federal Opioid Treatment Standards (42 CFR 8.12). See below for important regulatory exceptions to the general requirement for certification to provide opioid agonist treatment.

Failure to abide by the requirements in these regulations may result in criminal prosecution, seizure of the drug supply, revocation of the program approval, and injunction precluding operation of the program.

### Regulatory Exceptions To The General Requirement For Certification To Provide Opioid Agonist Treatment

During inpatient care, when the patient was admitted for any condition other than concurrent opioid addiction [pursuant to 21CFR 1306.07(c)], to facilitate the treatment of the primary admitting diagnosis.

During an emergency period of no longer than 3 days while definitive care for the addiction is being sought in an appropriately licensed facility [pursuant to 21CFR 1306.07(b)].

## Morphine Sulfate Extended-Release

Morphine Sulfate Extended-Release Capsules are indicated for the management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate.

### Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve Morphine Sulfate Extended-Release Capsules for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Morphine Sulfate Extended-Release Capsules are not indicated as an as-needed (prn) analgesic.

## MS Contin (morphine extended-release)

MS Contin is indicated for the management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate.

### Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve MS Contin for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- MS Contin is not indicated as an as-needed (prn) analgesic.

## Nucynta ER (tapentadol extended-release)

Nucynta ER (tapentadol) is indicated for the management of:

- Severe and persistent pain in adults that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate.
- Severe and persistent neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate.

### Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve Nucynta ER for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Nucynta ER is not indicated as an as-needed (prn) analgesic.

## OxyContin (oxycodone hydrochloride extended-release)

OxyContin is indicated for the management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate in:

- Adults; and
- Opioid-tolerant pediatric patients 11 years of age and older who are already receiving and tolerate a minimum daily opioid dose of at least 20 mg oxycodone orally or its equivalent.

### Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve Oxycontin for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are



ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.

- OxyContin is not indicated as an as-needed (prn) analgesic.

## Oxymorphone Hydrochloride Extended-Release

Oxymorphone hydrochloride extended-release tablets are indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

### Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve oxymorphone hydrochloride extended-release tablets for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Oxymorphone hydrochloride extended-release tablets are not indicated as an as-needed (prn) analgesic.

## Tramadol Hydrochloride Extended-Release

Tramadol hydrochloride extended-release tablets are indicated for the management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate.

### Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve tramadol hydrochloride extended-release tablets for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Tramadol hydrochloride extended-release tablets are not indicated as an as-needed (prn) analgesic.

## Xtampza ER (oxycodone extended-release)

Xtampza ER is indicated for the management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate.

### Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve Xtampza ER for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Xtampza ER is not indicated as an as-needed (prn) analgesic.

## 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.

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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) 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 ER Quantity Limits Chart below).

If the patient has filled a prescription for at least a 30-day supply of an 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 ER Quantity Limits Chart below).

If the patient does not have at least an 8-day supply of an IR opioid agent indicated for the management of pain OR at least a 30-day supply of an ER opioid agent indicated for the management of pain within prescription claim history in the past 90 days (i.e., the patient has not used an IR opioid prior to the ER opioid OR the patient is not already stable on an ER opioid), 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

[NOTE: These drugs should be prescribed only by healthcare professionals who are knowledgeable about the use of extended-release/long-acting 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.

### Chronic Pain

Authorization may be granted when the requested drug is being prescribed for CHRONIC pain severe and persistent enough to require an extended treatment period with a daily opioid analgesic in a patient who has been taking an opioid 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.]
- The patient meets ONE of the following:
  - This request is for continuation of therapy for a patient who has been receiving an extended-release opioid agent for at least 30 days.
  - The patient has taken an immediate-release opioid for at least one week.
- If the request is for a methadone product, then it is NOT being prescribed for detoxification treatment or as part of a maintenance treatment plan for opioid/substance abuse or addiction.

## Quantity Limits may Apply

### Opioid Analgesics ER Quantity Limits Chart

Coverage is provided without prior authorization for a 30-day or 90-day supply of an extended-release opioid for a quantity that corresponds to  $\leq 90$  morphine milligram equivalents (MME)/day (when Step Therapy criteria met). Coverage for quantities that correspond to  $\leq 200$  MME/day (unless FDA-labeled

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strength/dose/frequency exceeds 200 MME/day) for a 30-day or 90-day supply is provided through prior authorization when coverage conditions 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 post limit quantity is less than or equal to 200 MME per day, unless the minimum FDA-labeled strength/dose/frequency exceeds 200 MME/day.

For any drug with zero (0) listed in column A and column B, the initial limit is zero. All requests for this drug and strength will be considered through post limit prior authorization.

For methadone 10 mg/mL Intensol solution, in order to accommodate unbreakable packaging and refill processing, the fill limit is set up as a maximum quantity of 45 mL with a daily dose edit of 1.5 mL per day for column A only.

<b>Drug/Strength</b>	<b>Labeled Dosing</b>	<b>COLUMN A Initial 1 Month Limit ≤ 90 MME/day (per 25 days)</b>	<b>COLUMN B Initial 3 Month Limit ≤ 90 MME/day (per 75 days)</b>	<b>COLUMN C Post 1 Month Limit ≤ 200 MME/day (per 25 days)</b>	<b>COLUMN D Post 3 Month Limit ≤ 200 MME/day (per 75 days)</b>
Belbuca 75 mcg	once every 12 hours, MAX 900 mcg/12 hrs	60 films/month 2 films/day (4.5 MME/day)	180 films/3 months 2 films/day (4.5 MME/day)	90 films/month 3 films/day (6.75 MME/day)	270 films/3 months 3 films/day (6.75 MME/day)
Belbuca 150 mcg	once every 12 hours, MAX 900 mcg/12 hrs	60 films/month 2 films/day (9 MME/day)	180 films/3 months 2 films/day (9 MME/day)	90 films/month 3 films/day (13.5 MME/day)	270 films/3 months 3 films/day (13.5 MME/day)
Belbuca 300 mcg	once every 12 hours, MAX 900 mcg/12 hrs	60 films/month 2 films/day (18 MME/day)	180 films/3 months 2 films/day (18 MME/day)	90 films/month 3 films/day (27 MME/day)	270 films/3 months 3 films/day (27 MME/day)
Belbuca 450 mcg	once every 12 hours, MAX	60 films/month 2 films/day	180 films/3 months	90 films/month 3 films/day	270 films/3 months

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<b>Drug/Strength</b>	<b>Labeled Dosing</b>	<b>COLUMN A Initial 1 Month Limit ≤ 90 MME/day (per 25 days)</b>	<b>COLUMN B Initial 3 Month Limit ≤ 90 MME/day (per 75 days)</b>	<b>COLUMN C Post 1 Month Limit ≤ 200 MME/day (per 25 days)</b>	<b>COLUMN D Post 3 Month Limit ≤ 200 MME/day (per 75 days)</b>
	900 mcg/12 hrs	(27 MME/day)	2 films/day (27 MME/day)	(40.5 MME/day)	3 films/day (40.5 MME/day)
Belbuca 600 mcg	once every 12 hours, MAX 900 mcg/12 hrs	0	0	60 films/month 2 films/day (36 MME/day)	180 films/3 months 2 films/day (36 MME/day)
Belbuca 750 mcg	once every 12 hours, MAX 900 mcg/12 hrs	0	0	60 films/month 2 films/day (45 MME/day)	180 films/3 months 2 films/day (45 MME/day)
Belbuca 900 mcg	once every 12 hours, MAX 900 mcg/12 hrs	0	0	60 films/month 2 films/day (54 MME/day)	180 films/3 months 2 films/day (54 MME/day)
Butrans 5 mcg/hr	once every 7 days, MAX 20 mcg/hr	4 patches/month 0.144 patch/day (9 MME/day)	12 patches/3 months 0.144 patch/day (9 MME/day)	8 patches/month 0.287 patch/day (18 MME/day)	24 patches/3 months 0.287 patch/day (18 MME/day)
Butrans 7.5 mcg/hr	once every 7 days, MAX 20 mcg/hr	4 patches/month 0.144 patch/day (13.5 MME/day)	12 patches/3 months 0.144 patch/day (13.5 MME/day)	8 patches/month 0.287 patch/day (27 MME/day)	24 patches/3 months 0.287 patch/day (27 MME/day)
Butrans 10 mcg/hr	once every 7 days, MAX 20 mcg/hr	4 patches/month 0.144 patch/day (18 MME/day)	12 patches/3 months 0.144 patch/day (18 MME/day)	8 patches/month 0.287 patch/day (36 MME/day)	24 patches/3 months 0.287 patch/day (36 MME/day)
Butrans 15 mcg/hr	once every 7 days, MAX 20 mcg/hr	0	0	4 patches/month 0.144 patch/day (27 MME/day)	12 patches/3 months 0.144 patch/day (27 MME/day)

<b>Drug/Strength</b>	<b>Labeled Dosing</b>	<b>COLUMN A Initial 1 Month Limit ≤ 90 MME/day (per 25 days)</b>	<b>COLUMN B Initial 3 Month Limit ≤ 90 MME/day (per 75 days)</b>	<b>COLUMN C Post 1 Month Limit ≤ 200 MME/day (per 25 days)</b>	<b>COLUMN D Post 3 Month Limit ≤ 200 MME/day (per 75 days)</b>
Butrans 20 mcg/hr	once every 7 days, MAX 20 mcg/hr	0	0	4 patches/month 0.144 patch/day (36 MME/day)	12 patches/3 months 0.144 patch/day (36 MME/day)
ConZip 100 mg	once daily, MAX 300 mg/day	30 capsules/month 1 capsule/day (20 MME/day)	90 capsules/3 months 1 capsule/day (20 MME/day)	60 capsules/month 2 capsules/day (40 MME/day)	180 capsules/3 months 2 capsules/day (40 MME/day)
ConZip 200 mg	once daily, MAX 300 mg/day	0	0	30 capsules/month 1 capsule/day (40 MME/day)	90 capsules/3 months 1 capsule/day (40 MME/day)
ConZip 300 mg	once daily, MAX 300 mg/day	0	0	30 capsules/month 1 capsule/day (60 MME/day)	90 capsules/3 months 1 capsule/day (60 MME/day)
Fentanyl transdermal 12 mcg/hr	once every 72 hours	10 patches/month 0.334 patch/day (28.8 MME/day)	30 patches/3 months 0.334 patch/day (28.8 MME/day)	20 patches/month 0.667 patch/day (57.6 MME/day)	60 patches/3 months 0.667 patch/day (57.6 MME/day)
Fentanyl transdermal 25 mcg/hr	once every 72 hours	10 patches/month 0.334 patch/day (60 MME/day)	30 patches/3 months 0.334 patch/day (60 MME/day)	20 patches/month 0.667 patch/day (120 MME/day)	60 patches/3 months 0.667 patch/day (120 MME/day)
Fentanyl transdermal 37.5 mcg/hr	once every 72 hours	10 patches/month 0.334 patch/day (90 MME/day)	30 patches/3 months 0.334 patch/day (90 MME/day)	20 patches/month 0.667 patch/day (180 MME/day)	60 patches/3 months 0.667 patch/day (180 MME/day)
Fentanyl transdermal 50 mcg/hr	once every 72 hours	0	0	10 patches/month	30 patches/3 months

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				0.334 patch/day (120 MME/day)	0.334 patch/day (120 MME/day)
Fentanyl transdermal 62.5 mcg/hr	once every 72 hours	0	0	10 patches/month 0.334 patch/day (150 MME/day)	30 patches/3 months 0.334 patch/day (150 MME/day)
Fentanyl transdermal 75 mcg/hr	once every 72 hours	0	0	10 patches/month 0.334 patch/day (180 MME/day)	30 patches/3 months 0.334 patch/day (180 MME/day)
Fentanyl transdermal 87.5 mcg/hr	once every 72 hours	0	0	10 patches/month 0.334 patch/day (210 MME/day)	30 patches/3 months 0.334 patch/day (210 MME/day)
Fentanyl transdermal 100 mcg/hr	once every 72 hours	0	0	10 patches/month 0.334 patch/day (240 MME/day)	30 patches/3 months 0.334 patch/day (240 MME/day)
Hydrocodone ER (generic Zohydro ER) 10 mg	once every 12 hours	60 capsules/month 2 capsules/day (20 MME/day)	180 capsules/3 months 2 capsules/day (20 MME/day)	90 capsules/month 3 capsules/day (30 MME/day)	270 capsules/3 months 3 capsules/day (30 MME/day)
Hydrocodone ER (generic Zohydro ER) 15 mg	once every 12 hours	60 capsules/month 2 capsules/day (30 MME/day)	180 capsules/3 months 2 capsules/day (30 MME/day)	90 capsules/month 3 capsules/day (45 MME/day)	270 capsules/3 months 3 capsules/day (45 MME/day)
Hydrocodone ER (generic Zohydro ER) 20 mg	once every 12 hours	60 capsules/month 2 capsules/day (40 MME/day)	180 capsules/3 months 2 capsules/day (40 MME/day)	90 capsules/month 3 capsules/day (60 MME/day)	270 capsules/3 months 3 capsules/day (60 MME/day)

Reference number(s)
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<b>Drug/Strength</b>	<b>Labeled Dosing</b>	<b>COLUMN A Initial 1 Month Limit ≤ 90 MME/day (per 25 days)</b>	<b>COLUMN B Initial 3 Month Limit ≤ 90 MME/day (per 75 days)</b>	<b>COLUMN C Post 1 Month Limit ≤ 200 MME/day (per 25 days)</b>	<b>COLUMN D Post 3 Month Limit ≤ 200 MME/day (per 75 days)</b>
Hydrocodone ER (generic Zohydro ER) 30 mg	once every 12 hours	60 capsules/month 2 capsules/day (60 MME/day)	180 capsules/3 months 2 capsules/day (60 MME/day)	90 capsules/month 3 capsules/day (90 MME/day)	270 capsules/3 months 3 capsules/day (90 MME/day)
Hydrocodone ER (generic Zohydro ER) 40 mg	once every 12 hours	60 capsules/month 2 capsules/day (80 MME/day)	180 capsules/3 months 2 capsules/day (80 MME/day)	90 capsules/month 3 capsules/day (120 MME/day)	270 capsules/3 months 3 capsules/day (120 MME/day)
Hydrocodone ER (generic Zohydro ER) 50 mg	once every 12 hours	0	0	60 capsules/month 2 capsules/day (100 MME/day)	180 capsules/3 months 2 capsules/day (100 MME/day)
Hydromorphone ER (generic Exalgo) 8 mg	once daily	30 tablets/month 1 tablet/day (40 MME/day)	90 tablets/3 months 1 tablet/day (40 MME/day)	60 tablets/month 2 tablets/day (80 MME/day)	180 tablets/3 months 2 tablets/day (80 MME/day)
Hydromorphone ER (generic Exalgo) 12 mg	once daily	30 tablets/month 1 tablet/day (60 MME/day)	90 tablets/3 months 1 tablet/day (60 MME/day)	60 tablets/month 2 tablets/day (120 MME/day)	180 tablets/3 months 2 tablets/day (120 MME/day)
Hydromorphone ER (generic Exalgo) 16 mg	once daily	30 tablets/month 1 tablet/day (80 MME/day)	90 tablets/3 months 1 tablet/day (80 MME/day)	60 tablets/month 2 tablets/day (160 MME/day)	180 tablets/3 months 2 tablets/day (160 MME/day)
Hydromorphone ER (generic Exalgo) 32 mg	once daily	0	0	30 tablets/month 1 tablet/day (160 MME/day)	90 tablets/3 months 1 tablet/day (160 MME/day)
Hysingla ER 20 mg	once every 24 hours	30 tablets/month 1 tablet/day (20 MME/day)	90 tablets/3 months 1 tablet/day (20 MME/day)	60 tablets/month 2 tablets/day (40 MME/day)	180 tablets/3 months 2 tablets/day (40 MME/day)
Hysingla ER 30 mg	once every 24 hours	30 tablets/month 1 tablet/day (30 MME/day)	90 tablets/3 months 1 tablet/day (30 MME/day)	60 tablets/month 2 tablets/day (60 MME/day)	180 tablets/3 months 2 tablets/day (60 MME/day)



Reference number(s)
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<b>Drug/Strength</b>	<b>Labeled Dosing</b>	<b>COLUMN A Initial 1 Month Limit ≤ 90 MME/day (per 25 days)</b>	<b>COLUMN B Initial 3 Month Limit ≤ 90 MME/day (per 75 days)</b>	<b>COLUMN C Post 1 Month Limit ≤ 200 MME/day (per 25 days)</b>	<b>COLUMN D Post 3 Month Limit ≤ 200 MME/day (per 75 days)</b>
Hysingla ER 40 mg	once every 24 hours	30 tablets/month 1 tablet/day (40 MME/day)	90 tablets/3 months 1 tablet/day (40 MME/day)	60 tablets/month 2 tablets/day (80 MME/day)	180 tablets/3 months 2 tablets/day (80 MME/day)
Hysingla ER 60 mg	once every 24 hours	30 tablets/month 1 tablet/day (60 MME/day)	90 tablets/3 months 1 tablet/day (60 MME/day)	60 tablets/month 2 tablets/day (120 MME/day)	180 tablets/3 months 2 tablets/day (120 MME/day)
Hysingla ER 80 mg	once every 24 hours	30 tablets/month 1 tablet/day (80 MME/day)	90 tablets/3 months 1 tablet/day (80 MME/day)	60 tablets/month 2 tablets/day (160 MME/day)	180 tablets/3 months 2 tablets/day (160 MME/day)
Hysingla ER 100 mg	once every 24 hours	0	0	60 tablets/month 2 tablets/day (200 MME/day)	180 tablets/3 months 2 tablets/day (200 MME/day)
Hysingla ER 120 mg	once every 24 hours	0	0	30 tablets/month 1 tablet/day (120 MME/day)	90 tablets/3 months 1 tablet/day (120 MME/day)
Methadone 5 mg	once every 8 to 12 hours	90 tablets/month 3 tablets/day (70.5 MME/day)	270 tablets/3 months 3 tablets/day (70.5 MME/day)	120 tablets/month 4 tablets/day (94 MME/day)	360 tablets/3 months 4 tablets/day (94 MME/day)
Methadone 10 mg	once every 8 to 12 hours	30 tablets/month 1 tablet/day (47 MME/day)	90 tablets/3 months 1 tablet/day (47 MME/day)	90 tablets/month 3 tablets/day (141 MME/day)	270 tablets/3 months 3 tablets/day (141 MME/day)
Methadone 200 mg/20 mL injection	once every 8 to 12 hours	20 mL/month (1 multidose vial) 0.667 mL/day (31.3 MME/day)	60 mL/3 months (3 multidose vials) 0.667 mL/day (31.3 MME/day)	40 mL/month (2 multidose vials) 1.334 mL/day (62.7 MME/day)	120 mL/3 months (6 multidose vials) 1.334 mL/day (62.7 MME/day)

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<b>Drug/Strength</b>	<b>Labeled Dosing</b>	<b>COLUMN A Initial 1 Month Limit ≤ 90 MME/day (per 25 days)</b>	<b>COLUMN B Initial 3 Month Limit ≤ 90 MME/day (per 75 days)</b>	<b>COLUMN C Post 1 Month Limit ≤ 200 MME/day (per 25 days)</b>	<b>COLUMN D Post 3 Month Limit ≤ 200 MME/day (per 75 days)</b>
Methadone 10 mg/mL Intensol solution	once every 8 to 12 hours	45 mL/month 1.5 mL/day (70.5 MME/day)	135 mL/3 months 1.5 mL/day (70.5 MME/day)	90 mL/month 3 mL/day (141 MME/day)	270 mL/3 months 3 mL/day (141 MME/day)
Methadone 5 mg/5 mL Oral solution	once every 8 to 12 hours	450 mL/month 15 mL/day (70.5 MME/day)	1350 mL/3 months 15 mL/day (70.5 MME/day)	600 mL/month 20 mL/day (94 MME/day)	1800 mL/month 20 mL/day (94 MME/day)
Methadone 10 mg/5 mL Oral solution	once every 8 to 12 hours	225 mL/month 7.5 mL/day (70.5 MME/day)	675 mL/3 months 7.5 mL/day (70.5 MME/day)	450 mL/month 15 mL/day (141 MME/day)	1350 mL/3 months 15 mL/day (141 MME/day)
Morphine ER (generic Avinza) 30 mg	once every 24 hours, MAX 1600 mg/day	30 capsules/month 1 capsule/day (30 MME/day)	90 capsules/3 months 1 capsule/day (30 MME/day)	60 capsules/month 2 capsules/day (60 MME/day)	180 capsules/3 months 2 capsules/day (60 MME/day)
Morphine ER (generic Avinza) 45 mg	once every 24 hours, MAX 1600 mg/day	30 capsules/month 1 capsule/day (45 MME/day)	90 capsules/3 months 1 capsule/day (45 MME/day)	60 capsules/month 2 capsules/day (90 MME/day)	180 capsules/3 months 2 capsules/day (90 MME/day)
Morphine ER (generic Avinza) 60 mg	once every 24 hours, MAX 1600 mg/day	30 capsules/month 1 capsule/day (60 MME/day)	90 capsules/3 months 1 capsule/day (60 MME/day)	60 capsules/month 2 capsules/day (120 MME/day)	180 capsules/3 months 2 capsules/day (120 MME/day)
Morphine ER (generic Avinza) 75 mg	once every 24 hours, MAX 1600 mg/day	30 capsules/month 1 capsule/day (75 MME/day)	90 capsules/3 months 1 capsule/day (75 MME/day)	60 capsules/month 2 capsules/day (150 MME/day)	180 capsules/3 months 2 capsules/day (150 MME/day)
Morphine ER (generic Avinza) 90 mg	once every 24 hours, MAX 1600 mg/day	30 capsules/month 1 capsule/day (90 MME/day)	90 capsules/3 months 1 capsule/day (90 MME/day)	60 capsules/month 2 capsules/day (180 MME/day)	180 capsules/3 months 2 capsules/day (180 MME/day)
Morphine ER (generic Avinza) 120 mg	once every 24 hours, MAX 1600 mg/day	0	0	30 capsules/month 1 capsule/day (120 MME/day)	90 capsules/3 months 1 capsule/day (120 MME/day)

<b>Drug/Strength</b>	<b>Labeled Dosing</b>	<b>COLUMN A Initial 1 Month Limit ≤ 90 MME/day (per 25 days)</b>	<b>COLUMN B Initial 3 Month Limit ≤ 90 MME/day (per 75 days)</b>	<b>COLUMN C Post 1 Month Limit ≤ 200 MME/day (per 25 days)</b>	<b>COLUMN D Post 3 Month Limit ≤ 200 MME/day (per 75 days)</b>
Morphine ER (generic Kadian) 10 mg	once every 12 to 24 hours	60 capsules/month 2 capsules/day (20 MME/day)	180 capsules/3 months 2 capsules/day (20 MME/day)	90 capsules/month 3 capsules/day (30 MME/day)	270 capsules/3 months 3 capsules/day (30 MME/day)
Morphine ER (generic Kadian) 20 mg	once every 12 to 24 hours	60 capsules/month 2 capsules/day (40 MME/day)	180 capsules/3 months 2 capsules/day (40 MME/day)	90 capsules/month 3 capsules/day (60 MME/day)	270 capsules/3 months 3 capsules/day (60 MME/day)
Morphine ER (generic Kadian) 30 mg	once every 12 to 24 hours	60 capsules/month 2 capsules/day (60 MME/day)	180 capsules/3 months 2 capsules/day (60 MME/day)	90 capsules/month 3 capsules/day (90 MME/day)	270 capsules/3 months 3 capsules/day (90 MME/day)
Morphine ER (generic Kadian) 40 mg	once every 12 to 24 hours	60 capsules/month 2 capsules/day (80 MME/day)	180 capsules/3 months 2 capsules/day (80 MME/day)	90 capsules/month 3 capsules/day (120 MME/day)	270 capsules/3 months 3 capsules/day (120 MME/day)
Morphine ER (generic Kadian) 50 mg	once every 12 to 24 hours	30 capsules/month 1 capsule/day (50 MME/day)	90 capsules/3 months 1 capsule/day (50 MME/day)	60 capsules/month 2 capsules/day (100 MME/day)	180 capsules/3 months 2 capsules/day (100 MME/day)
Morphine ER (generic Kadian) 60 mg	once every 12 to 24 hours	30 capsules/month 1 capsule/day (60 MME/day)	90 capsules/3 months 1 capsule/day (60 MME/day)	60 capsules/month 2 capsules/day (120 MME/day)	180 capsules/3 months 2 capsules/day (120 MME/day)
Morphine ER (generic Kadian) 80 mg	once every 12 to 24 hours	30 capsules/month 1 capsule/day (80 MME/day)	90 capsules/3 months 1 capsule/day (80 MME/day)	60 capsules/month 2 capsules/day (160 MME/day)	180 capsules/3 months 2 capsules/day (160 MME/day)
Morphine ER (generic Kadian) 100 mg	once every 12 to 24 hours	0	0	60 capsules/month 2 capsules/day (200 MME/day)	180 capsules/3 months 2 capsules/day (200 MME/day)
MS Contin 15 mg	once every 8 to 12 hours	90 tablets/month 3 tablets/day (45 MME/day)	270 tablets/3 months 3 tablets/day (45 MME/day)	120 tablets/month 4 tablets/day (60 MME/day)	360 tablets/3 months 4 tablets/day (60 MME/day)

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<b>Drug/Strength</b>	<b>Labeled Dosing</b>	<b>COLUMN A Initial 1 Month Limit ≤ 90 MME/day (per 25 days)</b>	<b>COLUMN B Initial 3 Month Limit ≤ 90 MME/day (per 75 days)</b>	<b>COLUMN C Post 1 Month Limit ≤ 200 MME/day (per 25 days)</b>	<b>COLUMN D Post 3 Month Limit ≤ 200 MME/day (per 75 days)</b>
MS Contin 30 mg	once every 8 to 12 hours	90 tablets/month 3 tablets/day (90 MME/day)	270 tablets/3 months 3 tablets/day (90 MME/day)	120 tablets/month 4 tablets/day (120 MME/day)	360 tablets/3 months 4 tablets/day (120 MME/day)
MS Contin 60 mg	once every 8 to 12 hours	0	0	90 tablets/month 3 tablets/day (180 MME/day)	270 tablets/3 months 3 tablets/day (180 MME/day)
MS Contin 100 mg	once every 8 to 12 hours	0	0	60 tablets/month 2 tablets/day (200 MME/day)	180 tablets/3 months 2 tablets/day (200 MME/day)
MS Contin 200 mg	once every 8 to 12 hours	0	0	60 tablets/month 2 tablets/day (400 MME/day)	180 tablets/3 months 2 tablets/day (400 MME/day)
Nucynta ER 50 mg	once every 12 hours, MAX 500 mg/day	60 tablets/month 2 tablets/day (40 MME/day)	180 tablets/3 months 2 tablets/day (40 MME/day)	90 tablets/month 3 tablets/day (60 MME/day)	270 tablets/3 months 3 tablets/day (60 MME/day)
Nucynta ER 100 mg	once every 12 hours, MAX 500 mg/day	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)
Nucynta ER 150 mg	once every 12 hours, MAX 500 mg/day	0	0	90 tablets/month 3 tablets/day (180 MME/day)	270 tablets/3 months 3 tablets/day (180 MME/day)
Nucynta ER 200 mg	once every 12 hours, MAX 500 mg/day	0	0	60 tablets/month 2 tablets/day (160 MME/day)	180 tablets/3 months 2 tablets/day (160 MME/day)
Nucynta ER 250 mg	once every 12 hours, MAX 500 mg/day	0	0	60 tablets/month 2 tablets/day	180 tablets/3 months 2 tablets/day

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<b>Drug/Strength</b>	<b>Labeled Dosing</b>	<b>COLUMN A Initial 1 Month Limit ≤ 90 MME/day (per 25 days)</b>	<b>COLUMN B Initial 3 Month Limit ≤ 90 MME/day (per 75 days)</b>	<b>COLUMN C Post 1 Month Limit ≤ 200 MME/day (per 25 days)</b>	<b>COLUMN D Post 3 Month Limit ≤ 200 MME/day (per 75 days)</b>
				(200 MME/day)	(200 MME/day)
OxyContin 10 mg	once every 12 hours	60 tablets/month 2 tablets/day (30 MME/day)	180 tablets/3 months 2 tablets/day (30 MME/day)	90 tablets/month 3 tablets/day (45 MME/day)	270 tablets/3 months 3 tablets/day (45 MME/day)
OxyContin 15 mg	once every 12 hours	60 tablets/month 2 tablets/day (45 MME/day)	180 tablets/3 months 2 tablets/day (45 MME/day)	90 tablets/month 3 tablets/day (67.5 MME/day)	270 tablets/3 months 3 tablets/day (67.5 MME/day)
OxyContin 20 mg	once every 12 hours	60 tablets/month 2 tablets/day (60 MME/day)	180 tablets/3 months 2 tablets/day (60 MME/day)	90 tablets/month 3 tablets/day (90 MME/day)	270 tablets/3 months 3 tablets/day (90 MME/day)
OxyContin 30 mg	once every 12 hours	60 tablets/month 2 tablets/day (90 MME/day)	180 tablets/3 months 2 tablets/day (90 MME/day)	90 tablets/month 3 tablets/day (135 MME/day)	270 tablets/3 months 3 tablets/day (135 MME/day)
OxyContin 40 mg	once every 12 hours	0	0	90 tablets/month 3 tablets/day (180 MME/day)	270 tablets/3 months 3 tablets/day (180 MME/day)
OxyContin 60 mg	once every 12 hours	0	0	60 tablets/month 2 tablets/day (180 MME/day)	180 tablets/3 months 2 tablets/day (180 MME/day)
OxyContin 80 mg	once every 12 hours	0	0	60 tablets/month 2 tablets/day (240 MME/day)	180 tablets/3 months 2 tablets/day (240 MME/day)
Oxymorphone ER (generic Opana ER) 5 mg	once every 12 hours	60 tablets/month 2 tablets/day (30 MME/day)	180 tablets/3 months 2 tablets/day (30 MME/day)	90 tablets/month 3 tablets/day (45 MME/day)	270 tablets/3 months 3 tablets/day (45 MME/day)
Oxymorphone ER	once every 12 hours	60 tablets/month	180 tablets/3 months	90 tablets/month	270 tablets/3 months

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<b>Drug/Strength</b>	<b>Labeled Dosing</b>	<b>COLUMN A Initial 1 Month Limit ≤ 90 MME/day (per 25 days)</b>	<b>COLUMN B Initial 3 Month Limit ≤ 90 MME/day (per 75 days)</b>	<b>COLUMN C Post 1 Month Limit ≤ 200 MME/day (per 25 days)</b>	<b>COLUMN D Post 3 Month Limit ≤ 200 MME/day (per 75 days)</b>
(generic Opana ER) 7.5 mg		2 tablets/day (45 MME/day)	2 tablets/day (45 MME/day)	3 tablets/day (67.5 MME/day)	3 tablets/day (67.5 MME/day)
Oxymorphone ER (generic Opana ER) 10 mg	once every 12 hours	60 tablets/month 2 tablets/day (60 MME/day)	180 tablets/3 months 2 tablets/day (60 MME/day)	90 tablets/month 3 tablets/day (90 MME/day)	270 tablets/3 months 3 tablets/day (90 MME/day)
Oxymorphone ER (generic Opana ER) 15 mg	once every 12 hours	60 tablets/month 2 tablets/day (90 MME/day)	180 tablets/3 months 2 tablets/day (90 MME/day)	90 tablets/month 3 tablets/day (135 MME/day)	270 tablets/3 months 3 tablets/day (135 MME/day)
Oxymorphone ER (generic Opana ER) 20 mg	once every 12 hours	0	0	90 tablets/month 3 tablets/day (180 MME/day)	270 tablets/3 months 3 tablets/day (180 MME/day)
Oxymorphone ER (generic Opana ER) 30 mg	once every 12 hours	0	0	60 tablets/month 2 tablets/day (180 MME/day)	180 tablets/3 months 2 tablets/day (180 MME/day)
Oxymorphone ER (generic Opana ER) 40 mg	once every 12 hours	0	0	60 tablets/month 2 tablets/day (240 MME/day)	180 tablets/3 months 2 tablets/day (240 MME/day)
Tramadol ER (generic Ryzolt) 100 mg	once daily, MAX 300 mg/day	30 tablets/month 1 tablet/day (20 MME/day)	90 tablets/3 months 1 tablet/day (20 MME/day)	60 tablets/month 2 tablets/day (40 MME/day)	180 tablets/3 months 2 tablets/day (40 MME/day)
Tramadol ER (generic Ultram ER) 100 mg	once daily, MAX 300 mg/day	30 tablets/month 1 tablet/day (20 MME/day)	90 tablets/3 months 1 tablet/day (20 MME/day)	60 tablets/month 2 tablets/day (40 MME/day)	180 tablets/3 months 2 tablets/day (40 MME/day)
Tramadol ER (generic Ryzolt) 200 mg	once daily, MAX 300 mg/day	0	0	30 tablets/month 1 tablet/day	90 tablets/3 months 1 tablet/day

<b>Drug/Strength</b>	<b>Labeled Dosing</b>	<b>COLUMN A Initial 1 Month Limit ≤ 90 MME/day (per 25 days)</b>	<b>COLUMN B Initial 3 Month Limit ≤ 90 MME/day (per 75 days)</b>	<b>COLUMN C Post 1 Month Limit ≤ 200 MME/day (per 25 days)</b>	<b>COLUMN D Post 3 Month Limit ≤ 200 MME/day (per 75 days)</b>
				(40 MME/day)	(40 MME/day)
Tramadol ER (generic Ultram ER) 200 mg	once daily, MAX 300 mg/day	0	0	30 tablets/month 1 tablet/day (40 MME/day)	90 tablets/3 months 1 tablet/day (40 MME/day)
Tramadol ER (generic Ryzolt) 300 mg	once daily, MAX 300 mg/day	0	0	30 tablets/month 1 tablet/day (60 MME/day)	90 tablets/3 months 1 tablet/day (60 MME/day)
Tramadol ER (generic Ultram ER) 300 mg	once daily, MAX 300 mg/day	0	0	30 tablets/month 1 tablet/day (60 MME/day)	90 tablets/3 months 1 tablet/day (60 MME/day)
Xtampza ER 9 mg	once every 12 hours, MAX 288 mg/day	60 capsules/month 2 capsules/day (30 MME/day)	180 capsules/3 months 2 capsules/day (30 MME/day)	90 capsules/month 3 capsules/day (45 MME/day)	270 capsules/3 months 3 capsules/day (45 MME/day)
Xtampza ER 13.5 mg	once every 12 hours, MAX 288 mg/day	60 capsules/month 2 capsules/day (45 MME/day)	180 capsules/3 months 2 capsules/day (45 MME/day)	90 capsules/month 3 capsules/day (67.5 MME/day)	270 capsules/3 months 3 capsules/day (67.5 MME/day)
Xtampza ER 18 mg	once every 12 hours, MAX 288 mg/day	60 capsules/month 2 capsules/day (60 MME/day)	180 capsules/3 months 2 capsules/day (60 MME/day)	90 capsules/month 3 capsules/day (90 MME/day)	270 capsules/3 months 3 capsules/day (90 MME/day)
Xtampza ER 27 mg	once every 12 hours, MAX 288 mg/day	60 capsules/month 2 capsules/day (90 MME/day)	180 capsules/3 months 2 capsules/day (90 MME/day)	90 capsules/month 3 capsules/day (135 MME/day)	270 capsules/3 months 3 capsules/day (135 MME/day)
Xtampza ER 36 mg	once every 12 hours, MAX 288 mg/day	0	0	90 capsules/month 3 capsules/day (180 MME/day)	270 capsules/3 months 3 capsules/day (180 MME/day)

## Duration of Approval (DOA)

- 2219-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

## References

1. Belbuca [package insert]. Stoughton, MA: Collegium Pharmaceutical, Inc.; December 2023.
2. Butrans [package insert]. Stamford, CT: Purdue Pharma L.P.; December 2023.
3. ConZip [package insert]. Alpharetta, GA: Vertical Pharmaceuticals, LLC.; December 2023.
4. Fentanyl Transdermal [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; October 2024.
5. Hydrocodone ER capsules [package insert]. Morristown, NJ: Alvogen, Inc.; December 2023.
6. Hydromorphone ER [package insert]. Minneapolis, MN: Padagis; January 2024.
7. Hysingla ER [package insert]. Stamford, CT: Purdue Pharma L.P.; December 2023.
8. Methadone Injection [package insert]. Morgantown, WV: Mylan Institutional LLC; December 2023.
9. Methadone Hydrochloride Oral Concentrate (Intensol) [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; March 2024.
10. Methadone Oral Solution [package insert]. Webster Groves, MO: SpecGx LLC; January 2024.
11. Methadone Tablets [package insert]. Webster Groves, MO: SpecGx, LLC; December 2023.
12. Morphine ER Capsules [package insert]. Maple Grove, MN: Upsher-Smith Laboratories, LLC.; February 2024.
13. Morphine ER Capsules [package insert]. Parsippany, NJ: Teva Pharmaceuticals; November 2023.
14. MS Contin [package insert]. Stamford, CT: Purdue Pharma L.P.; December 2023.
15. Nucynta ER [package insert]. Stoughton, MA: Collegium Pharmaceutical, Inc; December 2023.
16. OxyContin [package insert]. Stamford, CT: Purdue Pharma L.P.; December 2023.
17. Oxymorphone ER [package insert]. Brookhaven, NY: Amneal Pharmaceuticals of NY, LLC; August 2022.
18. Tramadol extended-release tablets [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; December 2023.
19. Tramadol extended-release tablets [package insert]. Baltimore, MD: Lupin Pharmaceuticals, Inc.; January 2024.
20. Xtampza ER [package insert]. Cincinnati, OH: Patheon Pharmaceuticals; December 2023.
21. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed November 20, 2024.
22. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 11/20/2024).
23. 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 21, 2024.



Reference number(s)
2219-M

24. Palliative Care. NCCN Guidelines version 1.2025. Available at:  
[https://www.nccn.org/professionals/physician\\_gls/pdf/palliative.pdf](https://www.nccn.org/professionals/physician_gls/pdf/palliative.pdf). Accessed November 21, 2024.
25. Adult Cancer Pain. NCCN Guidelines version 3.2024. Available at:  
[https://www.nccn.org/professionals/physician\\_gls/pdf/pain.pdf](https://www.nccn.org/professionals/physician_gls/pdf/pain.pdf). Accessed December 9, 2024.
26. 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.
27. 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\\_O.pdf](https://www.nhlbi.nih.gov/sites/default/files/media/docs/sickle-cell-disease-report%20020816_O.pdf). Accessed November 21, 2024.
28. 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 November 21, 2024.