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## DRUG POLICY

# Extended Release Opioid Analgesics: Step Therapy with Quantity Limit and Post Limit Policy

### NOTICE

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

### BENEFIT APPLICATION

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

### DESCRIPTION

#### FDA-Approved Indications

#### **Arymo ER , Avinza, Kadian, MorphaBond ER, and MS Contin**

Arymo ER, Avinza, Kadian, MorphaBond ER, and MS Contin 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 Arymo ER, Avinza, Kadian, MorphaBond ER, and 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.
  - Arymo ER, Avinza, Kadian, MorphaBond ER, and MS Contin are not indicated as an as-needed (prn) analgesic.

#### **Belbuca and Butrans**

Belbuca and Butrans 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 long-acting opioid formulations, reserve Belbuca and 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 and Butrans are not indicated as an as-needed (prn) analgesic.

### **ConZip, Ultram ER, and Tramadol Hydrochloride Extended-Release**

ConZip, Ultram ER, and Tramadol Hydrochloride Extended-Release 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/long-acting opioid formulations, reserve ConZip, Ultram ER, and Tramadol Hydrochloride Extended-Release 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.
  - ConZip, Ultram ER, and Tramadol Hydrochloride Extended-Release is not indicated as an as-needed (prn) analgesic.

### **Dolophine Tablets**

Dolophine 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 long-acting opioids, reserve Dolophine 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.
    - Dolophine 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.

### **Duragesic**

Duragesic is indicated for the management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment 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 hydrocodone per day, or an equianalgesic dose of another opioid.

- 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/long-acting opioid formulations, reserve Duragesic 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.
  - Duragesic is not indicated as an as-needed (prn) analgesic.

### **Exalgo**

Exalgo is indicated for the management of pain in opioid-tolerant patients severe enough to require daily, around-the-clock, long-term opioid treatment 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, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve Exalgo 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.
  - Exalgo is not indicated as an as-needed (prn) analgesic.

### **Hysingla ER**

Hysingla ER is 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 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 Injection**

Methadone Injection is indicated:

- For the management of pain severe enough to require an opioid analgesic 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 reserve Methadone Hydrochloride Injection 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.
- 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.

### **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)].

### **Methadone Intensol**

Methadone Hydrochloride Intensol (oral concentrate) is 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 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 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.

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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)].

### **Methadone Oral Solution**

Methadone Hydrochloride Oral Solution is 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 Oral Solution 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 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 8.2.

### **Methadone Tablets**

Methadone Hydrochloride 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 long-acting opioids, 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 8.2.

### **Nucynta ER**

Nucynta ER is 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.
- Neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults 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 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.

### **Opana ER**

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

### **OxyContin**

OxyContin is 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 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 Usage
    - 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 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.

### **Targiniq ER**

Targiniq ER is 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 Targiniq 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.
  - Targiniq ER is not indicated as an as-needed (prn) analgesic.
  - The maximum total daily dose of Targiniq ER should not exceed 80 mg/40 mg (40 mg/20 mg q12h) because higher doses may be associated with symptoms of opioid withdrawal or decreased analgesia.

### **Troxyca ER**

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

### **Vantrela ER**

Vantrela ER is 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.

- Limitation 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 Vantrela 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.
  - Vantrela ER is not indicated as an as-needed (prn) analgesic.

### **Xtampza ER**

Xtampza ER is 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 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.

### **Zohydro ER**

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

## **POLICY**

### Screenout Logic

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

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

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

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

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

### Initial Step Therapy

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

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

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

**OR**

- The requested drug is being prescribed for CHRONIC pain severe enough to require daily, around-the-clock, long-term treatment in a patient who has been taking an opioid [Note: Chronic pain is generally defined as pain that typically lasts greater than 3 months.]

**AND**

- The patient can safely take the requested dose based on their history of opioid use

**AND**

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

**AND**

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

**AND**

- This request is for continuation of therapy for a patient who has been receiving an extended-release opioid agent for at least 30 days OR

- The patient has taken an immediate-release opioid for at least one week

**AND**

- 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

[Note: These drugs should be prescribed only by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain.]

Quantity Limits may apply.

Quantity Limits

<b>Opioid Analgesics ER Quantity Limits Chart</b>				
<p><b>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 ≤ 90 MME/day (when Step Therapy criteria met). Coverage for quantities that correspond to ≤ 200 MME/day (unless FDA-labeled 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.</b></p>				
<p><b>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).</b></p>				
	<b>COLUMN A</b>	<b>COLUMN B</b>	<b>COLUMN C</b>	<b>COLUMN D</b>

<b>Drug/Strength</b>	<b>Labeled Dosing</b>	<b>Initial 1 Month Limit*</b> <b>≤ 90 MME/day (per 25 days)</b>	<b>Initial 3 Month Limit*</b> <b>≤ 90 MME/day (per 75 days)</b>	<b>Post 1 Month Limit*</b> <b>≤ 200 MME/day**</b> <b>(per 25 days)</b>	<b>Post 3 Month Limit*</b> <b>≤ 200 MME/day**</b> <b>(per 75 days)</b>
Arymo ER 15 mg	q8-12h	90 tabs/month 3 tabs/day (45 MME/day)	270 tabs/3 months 3 tabs/day (45 MME/day)	120 tabs/month 4 tabs/day (60 MME/day)	360 tabs/3 months 4 tabs/day (60 MME/day)
Arymo ER 30 mg	q8-12h	90 tabs/month 3 tabs/day (90 MME/day)	270 tabs/3 months 3 tabs/day (90 MME/day)	120 tabs/month 4 tabs/day (120 MME/day)	360 tabs/3 months 4 tabs/day (120 MME/day)
Arymo ER 60 mg	q8-12h	0***	0***	90 tabs/month 3 tabs/day (180 MME/day)	270 tabs/3 months 3 tabs/day (180 MME/day)
Avinza 30 mg	q24h, MAX 1600 mg/day	30 caps/month 1 cap/day (30 MME/day)	90 caps/3 months 1 cap/day (30 MME/day)	60 caps/month 2 caps/day (60 MME/day)	180 caps/3 months 2 caps/day (60 MME/day)
Avinza 45 mg	q24h, MAX 1600 mg/day	30 caps/month 1 cap/day (45 MME/day)	90 caps/3 months 1 cap/day (45 MME/day)	60 caps/month 2 caps/day (90 MME/day)	180 caps/3 months 2 caps/day (90 MME/day)
Avinza 60 mg	q24h, MAX 1600 mg/day	30 caps/month 1 cap/day (60 MME/day)	90 caps/3 months 1 cap/day (60 MME/day)	60 caps/month 2 caps/day (120 MME/day)	180 caps/3 months 2 caps/day (120 MME/day)
Avinza 75 mg	q24h, MAX 1600 mg/day	30 caps/month 1 cap/day (75 MME/day)	90 caps/3 months 1 cap/day (75 MME/day)	60 caps/month 2 caps/day (150 MME/day)	180 caps/3 months 2 caps/day (150 MME/day)
Avinza 90 mg	q24h, MAX 1600 mg/day	30 caps/month 1 cap/day (90 MME/day)	90 caps/3 months 1 cap/day (90 MME/day)	60 caps/month 2 caps/day (180 MME/day)	180 caps/3 months 2 caps/day (180 MME/day)
Avinza 120 mg	q24h, MAX 1600 mg/day	0***	0***	30 caps/month 1 cap/day	90 caps/3 months

				(120 MME/day)	1 cap/day (120 MME/day)
Belbuca 75 mcg	q12h, 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	q12h, 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	q12h, 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	q12h, MAX 900 mcg/12 hrs	60 films/month 2 films/day (27 MME/day)	180 films 2 films/day (27 MME/day)	90 films/month 3 films/day (40.5 MME/day)	270 films/3 months 3 films/day (40.5 MME/day)
Belbuca 600 mcg	q12h, 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	q12h, 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	q12h, 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	q7d, 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	q7d, MAX 20 mcg/hr	4 patches/month 0.144 patch/day (13.5 MME/day)	12 patches/3 months 0.144 patch/day	8 patches/month 0.287 patch/day	24 patches/3 months 0.287 patch/day

			(13.5 MME/day)	(27 MME/day)	(27 MME/day)
Butrans 10 mcg/hr	q7d, 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	q7d, 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)
Butrans 20 mcg/hr	q7d, 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	qd, MAX 300 mg/day	30 caps/month 1 cap/day (10 MME/day)	90 caps/3 months 1 cap/day (10 MME/day)	60 caps/month 2 caps/day (20 MME/day)	180 caps/3 months 2 caps/day (20 MME/day)
ConZip 200 mg	qd, MAX 300 mg/day	0***	0***	30 caps/month 1 cap/day (20 MME/day)	90 caps/3 months 1 cap/day (20 MME/day)
ConZip 300 mg	qd, MAX 300 mg/day	0***	0***	30 caps/month 1 caps/day (30 MME/day)	90 caps/3 months 1 cap/day (30 MME/day)
Dolophine 5 mg****	q8-12h	90 tabs/month 3 tabs/day (60 MME/day)	270 tabs/3 months 3 tabs/day (60 MME/day)	120 tabs/month 4 tabs/day (80 MME/day)	360 tabs/3 months 4 tabs/day (80 MME/day)
Dolophine 10 mg****	q8-12h	60 tabs/month 2 tabs/day (80 MME/day)	180 tabs/3 months 2 tabs/day (80 MME/day)	90 tabs/month 3 tabs/day (240 MME/day)	270 tabs/3 months 3 tabs/day (240 MME/day)
Duragesic 12 mcg/hr	q72h	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)
Duragesic 25 mcg/hr	q72h	10 patches/month	30 patches/3 months	20 patches/month	60 patches/3 months

		0.334 patch/day (60 MME/day)	0.334 patch/day (60 MME/day)	0.667 patch/day (120 MME/day)	0.667 patch/day (120 MME/day)
Duragesic 37.5 mcg/hr	q72h	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)
Duragesic 50 mcg/hr	q72h	0***	0***	10 patches/month 0.334 patch/day (120 MME/day)	30 patches/3 months 0.334 patch/day (120 MME/day)
Duragesic 62.5 mcg/hr	q72h	0***	0***	10 patches/month 0.334 patch/day (150 MME/day)	30 patches/3 months 0.334 patch/day (150 MME/day)
Duragesic 75 mcg/hr	q72h	0***	0***	10 patches/month 0.334 patch/day (180 MME/day)	30 patches/3 months 0.334 patch/day (180 MME/day)
Duragesic 87.5 mcg/hr	q72h	0***	0***	10 patches/month 0.334 patch/day (210 MME/day)	30 patches/3 months 0.334 patch/day (210 MME/day)
Duragesic 100 mcg/hr	q72h	0***	0***	10 patches/month 0.334 patch/day (240 MME/day)	30 patches/3 months 0.334 patch/day (240 MME/day)
Exalgo 8 mg	qd	30 tabs/month 1 tab/day (32 MME/day)	90 tabs/3 months 1 tab/day (32 MME/day)	60 tabs/month 2 tabs/day (64 MME/day)	180 tabs/3 months 2 tabs/day (64 MME/day)
Exalgo 12 mg	qd	30 tabs/month 1 tab/day (48 MME/day)	90 tabs/3 months 1 tab/day (48 MME/day)	60 tabs/month 2 tabs/day (96 MME/day)	180 tabs/3 months 2 tabs/day (96 MME/day)
Exalgo 16 mg	qd	30 tabs/month 1 tab/day (64 MME/day)	90 tabs/3 months 1 tab/day (64 MME/day)	60 tabs/month 2 tabs/day (128 MME/day)	180 tabs/3 months 2 tabs/day (128 MME/day)

Exalgo 32 mg	qd	0***	0***	30 tabs/month 1 tab/day (128 MME/day)	90 tabs/3 months 1 tab/day (128 MME/day)
Hysingla ER 20 mg	q24h	30 tabs/month 1 tab/day (20 MME/day)	90 tabs/3 months 1 tab/day (20 MME/day)	60 tabs/month 2 tabs/day (40 MME/day)	180 tabs/3 months 2 tabs/day (40 MME/day)
Hysingla ER 30 mg	q24h	30 tabs/month 1 tab/day (30 MME/day)	90 tabs/3 months 1 tab/day (30 MME/day)	60 tabs/month 2 tabs/day (60 MME/day)	180 tabs/3 months 2 tabs/day (60 MME/day)
Hysingla ER 40 mg	q24h	30 tabs/month 1 tab/day (40 MME/day)	90 tabs/3 months 1 tab/day (40 MME/day)	60 tabs/month 2 tabs/day (80 MME/day)	180 tabs/3 months 2 tabs/day (80 MME/day)
Hysingla ER 60 mg	q24h	30 tabs/month 1 tab/day (60 MME/day)	90 tabs/3 months 1 tab/day (60 MME/day)	60 tabs/month 2 tabs/day (120 MME/day)	180 tabs/3 months 2 tabs/day (120 MME/day)
Hysingla ER 80 mg	q24h	30 tabs/month 1 tab/day (80 MME/day)	90 tabs/3 months 1 tab/day (80 MME/day)	60 tabs/month 2 tabs/day (160 MME/day)	180 tabs/3 months 2 tabs/day (160 MME/day)
Hysingla ER 100 mg	q24h	0***	0***	60 tabs/month 2 tabs/day (200 MME/day)	180 tabs/3 months 2 tabs/day (200 MME/day)
Hysingla ER 120 mg	q24h	0***	0***	30 tabs/month 1 tab/day (120 MME/day)	90 tabs/3 months 1 tab/day (120 MME/day)
Kadian 10 mg	q12-24h	60 caps/month 2 caps/day (20 MME/day)	180 caps/3 months 2 caps/day (20 MME/day)	90 caps/month 3 caps/day (30 MME/day)	270 caps/3 months 3 caps/day (30 MME/day)
Kadian 20 mg	q12-24h	60 caps/month 2 caps/day (40 MME/day)	180 caps/3 months 2 caps/day (40 MME/day)	90 caps/month 3 caps/day (60 MME/day)	270 caps/3 months 3 caps/day

					(60 MME/day)
Kadian 30 mg	q12-24h	60 caps/month 2 caps/day (60 MME/day)	180 caps/3 months 2 caps/day (60 MME/day)	90 caps/month 3 caps/day (90 MME/day)	270 caps/3 months 3 caps/day (90 MME/day)
Kadian 40 mg	q12-24h	60 caps/month 2 caps/day (80 MME/day)	180 caps/3 months 2 caps/day (80 MME/day)	90 caps/month 3 caps/day (120 MME/day)	270 caps/3 months 3 caps/day (120 MME/day)
Kadian 50 mg	q12-24h	30 caps/month 1 cap/day (50 MME/day)	90 caps/3 months 1 cap/day (50 MME/day)	60 caps/month 2 caps/day (100 MME/day)	180 caps/3 months 2 caps/day (100 MME/day)
Kadian 60 mg	q12-24h	30 caps/month 1 cap/day (60 MME/day)	90 caps/3 months 1 cap/day (60 MME/day)	60 caps/month 2 caps/day (120 MME/day)	180 caps/3 months 2 caps/day (120 MME/day)
Kadian 80 mg	q12-24h	30 caps/month 1 cap/day (80 MME/day)	90 caps/3 months 1 cap/day (80 MME/day)	60 caps/month 2 caps/day (160 MME/day)	180 caps/3 months 2 caps/day (160 MME/day)
Kadian 100 mg	q12-24h	0***	0***	60 caps/month 2 caps/day (200 MME/day)	180 caps/3 months 2 caps/day (200 MME/day)
Kadian 200 mg	q12-24h	0***	0***	30 caps/month 1 cap/day (200 MME/day)	90 caps/3 months 1 cap/day (200 MME/day)
Methadone 5 mg****	q8-12h	90 tabs/month 3 tabs/day (60 MME/day)	270 tabs/3 months 3 tabs/day (60 MME/day)	120 tabs/month 4 tabs/day (80 MME/day)	360 tabs/3 months 4 tabs/day (80 MME/day)
Methadone 10 mg****	q8-12h	60 tabs/month 2 tabs/day (80 MME/day)	180 tabs/3 months 2 tabs/day (80 MME/day)	90 tabs/month 3 tabs/day (240 MME/day)	270 tabs/3 months 3 tabs/day (240 MME/day)
Methadone 200 mg/20 mL injection****	q8-12h	20 mL/month (1 multidose vial)	60 mL/3 months (3 multidose vials)	40 mL/month	120 mL/3 months

		0.667 mL/day (26.7 MME/day)	0.667 mL/day (26.7 MME/day)	(2 multidose vials) 1.334 mL/day (53.3 MME/day)	(6 multidose vials) 1.334 mL/day (53.3 MME/day)
Methadone 10 mg/mL Intenso soln****	q8-12h	60 mL/month 2 mL/day (80 MME/day)	180 mL/3 months 2 mL/day (80 MME/day)	90 mL/month 3 mL/day (240 MME/day)	270 mL/3 months 3 mL/day (240 MME/day)
Methadone 5 mg/5 mL Oral soln****	q8-12h	450 mL/month 15 mL/day (60 MME/day)	1350 mL/3 months 15 mL/day (60 MME/day)	600 mL/month 20 mL/day (80 MME/day)	1800 mL/month 20 mL/day (80 MME/day)
Methadone 10 mg/5 mL Oral soln****	q8-12h	300 mL/month 10 mL/day (80 MME/day)	900 mL/3 months 10 mL/day (80 MME/day)	450 mL/month 15 mL/day (240 MME/day)	1350 mL/3 months 15 mL/day (240 MME/day)
MorphaBond ER 15 mg	q8-12h	90 tabs/month 3 tabs/day (45 MME/day)	270 tabs/3 months 3 tabs/day (45 MME/day)	120 tabs/month 4 tabs/day (60 MME/day)	360 tabs/3 months 4 tabs/day (60 MME/day)
MorphaBond ER 30 mg	q8-12h	90 tabs/month 3 tabs/day (90 MME/day)	270 tabs/3 months 3 tabs/day (90 MME/day)	120 tabs/month 4 tabs/day (120 MME/day)	360 tabs/3 months 4 tabs/day (120 MME/day)
MorphaBond ER 60 mg	q8-12h	0***	0***	90 tabs/month 3 tabs/day (180 MME/day)	270 tabs/3 months 3 tabs/day (180 MME/day)
MorphaBond ER 100 mg	q8-12h	0***	0***	60 tabs/month 2 tabs/day (200 MME/day)	180 tabs/3 months 2 tabs/day (200 MME/day)
MS Contin 15 mg	q8-12h	90 tabs/month 3 tabs/day (45 MME/day)	270 tabs/3 months 3 tabs/day (45 MME/day)	120 tabs/month 4 tabs/day (60 MME/day)	360 tabs/3 months 4 tabs/day (60 MME/day)
MS Contin 30 mg	q8-12h	90 tabs/month 3 tabs/day (90 MME/day)	270 tabs/3 months 3 tabs/day (90 MME/day)	120 tabs/month 4 tabs/day (120 MME/day)	360 tabs/3 months 4 tabs/day (120 MME/day)

MS Contin 60 mg	q8-12h	0***	0***	90 tabs/month 3 tabs/day (180 MME/day)	270 tabs/3 months 3 tabs/day (180 MME/day)
MS Contin 100 mg	q8-12h	0***	0***	60 tabs/month 2 tabs/day (200 MME/day)	180 tabs/3 months 2 tabs/day (200 MME/day)
MS Contin 200 mg	q8-12h	0***	0***	60 tabs/month 2 tabs/day (400 MME/day)	180 tabs/3 months 2 tabs/day (400 MME/day)
Nucynta ER 50 mg	q12h, MAX 500 mg/day	60 tabs/month 2 tabs/day (40 MME/day)	180 tabs/3 months 2 tabs/day (40 MME/day)	90 tabs/month 3 tabs/day (60 MME/day)	270 tabs/3 months 3 tabs/day (60 MME/day)
Nucynta ER 100 mg	q12h, MAX 500 mg/day	60 tabs/month 2 tabs/day (80 MME/day)	180 tabs/3 months 2 tabs/day (80 MME/day)	90 tabs/month 3 tabs/day (120 MME/day)	270 tabs/3 months 3 tabs/day (120 MME/day)
Nucynta ER 150 mg	q12h, MAX 500 mg/day	0***	0***	90 tabs/month 3 tabs/day (180 MME/day)	270 tabs/3 months 3 tabs/day (180 MME/day)
Nucynta ER 200 mg	q12h, MAX 500 mg/day	0***	0***	60 tabs/month 2 tabs/day (160 MME/day)	180 tabs/3 months 2 tabs/day (160 MME/day)
Nucynta ER 250 mg	q12h, MAX 500 mg/day	0***	0***	60 tabs/month 2 tabs/day (200 MME/day)	180 tabs/3 months 2 tabs/day (200 MME/day)
Opana ER 5 mg	q12h	60 tabs/month 2 tabs/day (30 MME/day)	180 tabs/3 months 2 tabs/day (30 MME/day)	90 tabs/month 3 tabs/day (45 MME/day)	270 tabs/3 months 3 tabs/day (45 MME/day)
Opana ER 7.5 mg	q12h	60 tabs/month 2 tabs/day (45 MME/day)	180 tabs/3 months 2 tabs/day (45 MME/day)	90 tabs/month 3 tabs/day (67.5 MME/day)	270 tabs/3 months 3 tabs/day

					(67.5 MME/day)
Opana ER 10 mg	q12h	60 tabs/month 2 tabs/day (60 MME/day)	180 tabs/3 months 2 tabs/day (60 MME/day)	90 tabs/month 3 tabs/day (90 MME/day)	270 tabs/3 months 3 tabs/day (90 MME/day)
Opana ER 15 mg	q12h	60 tabs/month 2 tabs/day (90 MME/day)	180 tabs/3 months 2 tabs/day (90 MME/day)	90 tabs/month 3 tabs/day (135 MME/day)	270 tabs/3 months 3 tabs/day (135 MME/day)
Opana ER 20 mg	q12h	0***	0***	90 tabs/month 3 tabs/day (180 MME/day)	270 tabs/3 months 3 tabs/day (180 MME/day)
Opana ER 30 mg	q12h	0***	0***	60 tabs/month 2 tabs/day (180 MME/day)	180 tabs/3 months 2 tabs/day (180 MME/day)
Opana ER 40 mg	q12h	0***	0***	60 tabs/month 2 tabs/day (240 MME/day)	180 tabs/3 months 2 tabs/day (240 MME/day)
OxyContin 10 mg	q12h	60 tabs/month 2 tabs/day (30 MME/day)	180 tabs/3 months 2 tabs/day (30 MME/day)	90 tabs/month 3 tabs/day (45 MME/day)	270 tabs/3 months 3 tabs/day (45 MME/day)
OxyContin 15 mg	q12h	60 tabs/month 2 tabs/day (45 MME/day)	180 tabs/3 months 2 tabs/day (45 MME/day)	90 tabs/month 3 tabs/day (67.5 MME/day)	270 tabs/3 months 3 tabs/day (67.5 MME/day)
OxyContin 20 mg	q12h	60 tabs/month 2 tabs/day (60 MME/day)	180 tabs/3 months 2 tabs/day (60 MME/day)	90 tabs/month 3 tabs/day (90 MME/day)	270 tabs/3 months 3 tabs/day (90 MME/day)
OxyContin 30 mg	q12h	60 tabs/month 2 tabs/day (90 MME/day)	180 tabs/3 months 2 tabs/day (90 MME/day)	90 tabs/month 3 tabs/day (135 MME/day)	270 tabs/3 months 3 tabs/day (135 MME/day)

OxyContin 40 mg	q12h	0***	0***	90 tabs/month 3 tabs/day (180 MME/day)	270 tabs/3 months 3 tabs/day (180 MME/day)
OxyContin 60 mg	q12h	0***	0***	60 tabs/month 2 tabs/day (180 MME/day)	180 tabs/3 months 2 tabs/day (180 MME/day)
OxyContin 80 mg	q12h	0***	0***	60 tabs/month 2 tabs/day (240 MME/day)	180 tabs/3 months 2 tabs/day (240 MME/day)
Targiniq ER 10 mg/5 mg	q12h, MAX 80 mg/40 mg (40 mg/20 mg q12h)	60 tabs/month 2 tabs/day (30 MME/day)	180 tabs/3 months 2 tabs/day (30 MME/day)	90 tabs/month 3 tabs/day (45 MME/day)	270 tabs/3 months 3 tabs/day (45 MME/day)
Targiniq ER 20 mg/10 mg	q12h, MAX 80 mg/40 mg (40 mg/20 mg q12h)	60 tabs/month 2 tabs/day (60 MME/day)	180 tabs/3 months 2 tabs/day (60 MME/day)	90 tabs/month 3 tabs/day (90 MME/day)	270 tabs/3 months 3 tabs/day (90 MME/day)
Targiniq ER 40 mg/20 mg	q12h, MAX 80 mg/40 mg (40 mg/20 mg q12h)	0***	0***	60 tabs/month 2 tabs/day (120 MME/day)	180 tabs/3 months 2 tabs/day (120 MME/day)
Tramadol ER 100 mg	qd, MAX 300 mg/day	30 tabs/month 1 tab/day (10 MME/day)	90 tabs/3 months 1 tab/day (10 MME/day)	60 tabs/month 2 tabs/day (20 MME/day)	180 tabs/3 months 2 tabs/day (20 MME/day)
Tramadol ER 150 mg	qd, MAX 300 mg/day	30 caps 1 cap/day (15 MME/day)	90 caps/3 months 1 cap/day (15 MME/day)	60 caps/month 2 caps/day (30 MME/day)	180 caps/3 months 2 caps/day (30 MME/day)
Tramadol ER 200 mg	qd, MAX 300 mg/day	0***	0***	30 tabs/month 1 tab/day (20 MME/day)	90 tabs/3 months 1 tab/day (20 MME/day)
Tramadol ER 300 mg	qd, MAX 300 mg/day	0***	0***	30 tabs/month 1 tab/day (30 MME/day)	90 tabs/3 months 1 tab/day

					(30 MME/day)
Troxyca ER 10 mg/1.2 mg	q12h	60 caps/month 2 caps/day (30 MME/day)	180 caps/3 months 2 caps/day (30 MME/day)	90 caps/month 3 caps/day (45 MME/day)	270 caps/3 months 3 caps/day (45 MME/day)
Troxyca ER 20 mg/2.4 mg	q12h	60 caps/month 2 caps/day (60 MME/day)	180 caps/3 months 2 caps/day (60 MME/day)	90 caps/month 3 caps/day (90 MME/day)	270 caps/3 months 3 caps/day (90 MME/day)
Troxyca ER 30 mg/3.6 mg	q12h	60 caps/month 2 caps/day (90 MME/day)	180 caps/3 months 2 caps/day (90 MME/day)	90 caps/month 3 caps/day (135 MME/day)	270 caps/3 months 3 caps/day (135 MME/day)
Troxyca ER 40 mg/4.8 mg	q12h	0***	0***	90 caps/month 3 caps/day (180 MME/day)	270 caps/3 months 3 caps/day (180 MME/day)
Troxyca ER 60 mg/7.2 mg	q12h	0***	0***	60 caps/month 2 caps/day (180 MME/day)	180 caps/3 months 2 caps/day (180 MME/day)
Troxyca ER 80 mg/9.6 mg	q12h	0***	0***	60 caps/month 2 caps/day (240 MME/day)	180 caps/3 months 2 caps/day (240 MME/day)
Ultram ER 100 mg	qd, MAX 300 mg/day	30 tabs/month 1 tab/day (10 MME/day)	90 tabs/3 months 1 tab/day (10 MME/day)	60 tabs/month 2 tabs/day (20 MME/day)	180 tabs/3 months 2 tabs/day (20 MME/day)
Ultram ER 200 mg	qd, MAX 300 mg/day	0***	0***	30 tabs/month 1 tab/day (20 MME/day)	90 tabs/3 months 1 tab/day (20 MME/day)
Ultram ER 300 mg	qd, MAX 300 mg/day	0***	0***	30 tabs/month 1 tab/day (30 MME/day)	90 tabs/3 months 1 tab/day (30 MME/day)

Vantrela ER 15 mg	q12h, MAX 90 mg q12h (180 mg/day)	60 tabs/month 2 tabs/day (30 MME/day)	180 tabs/3 months 2 tabs/day (30 MME/day)	90 tabs/month 3 tabs/day (45 MME/day)	270 tabs/3 months 3 tabs/day (45 MME/day)
Vantrela ER 30 mg	q12h, MAX 90 mg q12h (180 mg/day)	60 tabs/month 2 tabs/day (60 MME/day)	180 tabs/3 months 2 tabs/day (60 MME/day)	90 tabs/month 3 tabs/day (90 MME/day)	270 tabs/3 months 3 tabs/day (90 MME/day)
Vantrela ER 45 mg	q12h, MAX 90 mg q12h (180 mg/day)	60 tabs/month 2 tabs/day (90 MME/day)	180 tabs/3 months 2 tabs/day (90 MME/day)	90 tabs/month 3 tabs/day (135 MME/day)	270 tabs/3 months 3 tabs/day (135 MME/day)
Vantrela ER 60 mg	q12h, MAX 90 mg q12h (180 mg/day)	0***	0***	60 tabs/month 2 tabs/day (120 MME/day)	180 tabs/3 months 2 tabs/day (120 MME/day)
Vantrela ER 90 mg	q12h, MAX 90 mg q12h (180 mg/day)	0***	0***	60 tabs/month 2 tabs/day (180 MME/day)	180 tabs/3 months 2 tabs/day (180 MME/day)
Xtampza ER 9 mg	q12h, MAX 288 mg/day	60 caps/month 2 caps/day (30 MME/day)	180 caps/3 months 2 caps/day (30 MME/day)	90 caps/month 3 caps/day (45 MME/day)	270 caps/3 months 3 caps/day (45 MME/day)
Xtampza ER 13.5 mg	q12h, MAX 288 mg/day	60 caps/month 2 caps/day (45 MME/day)	180 caps/3 months 2 caps/day (45 MME/day)	90 caps/month 3 caps/day (67.5 MME/day)	270 caps/3 months 3 caps/day (67.5 MME/day)
Xtampza ER 18 mg	q12h, MAX 288 mg/day	60 caps/month 2 caps/day (60 MME/day)	180 caps/3 months 2 caps/day (60 MME/day)	90 caps/month 3 caps/day (90 MME/day)	270 caps/3 months 3 caps/day (90 MME/day)
Xtampza ER 27 mg	q12h, MAX 288 mg/day	60 caps/month 2 caps/day (90 MME/day)	180 caps/3 months 2 caps/day (90 MME/day)	90 caps/month 3 caps/day (135 MME/day)	270 caps/3 months 3 caps/day (135 MME/day)
Xtampza ER 36 mg	q12h, MAX 288 mg/day	0***	0***	90 caps/month 3 caps/day (180 MME/day)	270 caps/3 months 3 caps/day

					(180 MME/day)
Zohydro ER 10 mg	q12h	60 caps/month 2 caps/day (20 MME/day)	180 caps/3 months 2 caps/day (20 MME/day)	90 caps/month 3 caps/day (30 MME/day)	270 caps/3 months 3 caps/day (30 MME/day)
Zohydro ER 15 mg	q12h	60 caps/month 2 caps/day (30 MME/day)	180 caps/3 months 2 caps/day (30 MME/day)	90 caps/month 3 caps/day (45 MME/day)	270 caps/3 months 3 caps/day (45 MME/day)
Zohydro ER 20 mg	q12h	60 caps/month 2 caps/day (40 MME/day)	180 caps/3 months 2 caps/day (40 MME/day)	90 caps/month 3 caps/day (60 MME/day)	270 caps/3 months 3 caps/day (60 MME/day)
Zohydro ER 30 mg	q12h	60 caps/month 2 caps/day (60 MME/day)	180 caps/3 months 2 caps/day (60 MME/day)	90 caps/month 3 caps/day (90 MME/day)	270 caps/3 months 3 caps/day (90 MME/day)
Zohydro ER 40 mg	q12h	60 caps/month 2 caps/day (80 MME/day)	180 caps/3 months 2 caps/day (80 MME/day)	90 caps/month 3 caps/day (120 MME/day)	270 caps/3 months 3 caps/day (120 MME/day)
Zohydro ER 50 mg	q12h	0***	0***	60 caps/month 2 caps/day (100 MME/day)	180 caps/3 months 2 caps/day (100 MME/day)

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

\*\*Unless minimum FDA-labeled strength/dose/frequency exceeds 200 MME/day.

\*\*\*The initial limit is zero. All requests for this drug and strength will be considered through post limit prior authorization.

\*\*\*\*Calculating MME for methadone in clinical practice often involves a sliding-scale approach whereby the conversion factor increases with increasing dose.

## CLINICAL RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Extended-release opioids 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. 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 extended-release opioids 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. Extended-release opioids are not indicated as as-needed (prn) analgesics. These drugs should be prescribed only by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain.<sup>1-30</sup>

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

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

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

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

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

For patients with no prescription claims of a cancer drug or a sickle cell disease drug in the past 365 days, no ICD 10 diagnosis code indicating cancer, sickle cell disease, or palliative care submitted with their prescription claim, no ICD 10 diagnosis code indicating cancer or palliative care in 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.

The Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain provides recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, sickle cell disease, palliative care, and end-of-life care.<sup>31</sup>

The National Comprehensive Cancer Network (NCCN) guidelines for Adult Cancer Pain recommend for continuous pain, it is appropriate to give pain medication on a regular schedule with supplemental doses for breakthrough pain. Add an extended-release or long-acting formulation to provide background analgesia for control of chronic persistent pain controlled on stable doses of short-acting opioids. Allow rescue doses of short-acting opioids up to every 1 hour as needed.<sup>33</sup>

The NCCN Palliative Care pain management recommendation is to treat according to NCCN guidelines for adult cancer pain.<sup>32</sup> For patients with no prescription claims of a cancer drug in the past 365 days, no ICD 10 diagnosis code indicating cancer or palliative care submitted with their prescription claim, no ICD 10 diagnosis code indicating cancer or palliative care in their member health profile in the past 365 days, or no hospice patient residence code submitted with their prescription claim who are identified through the prior authorization criteria as having cancer, a terminal condition, or pain being managed through hospice or palliative care, step therapy criteria and post limit quantities will not apply.

According to the National Heart, Lung, and Blood Institute's (NHLBI) guidelines for Sickle Cell Disease (SCD), pain is the most common symptom of SCD. Pain can be acute, chronic, or an acute episode superimposed on chronic pain. Recurrent acute pain crises (also known as vaso-occlusive crises) are the most common manifestation of SCD. Chronic pain is also one of the most common chronic complications of SCD. Pain management must be guided by patient report of severity. No biomarkers or imaging studies can validate pain or assess its severity. Medications used to treat SCD-related pain should be tailored to the individual. For pain that is not relieved by nonsteroidal anti-inflammatory drugs (NSAIDs) or other measures, either short-acting or long-acting opioids may be used to manage pain in SCD.<sup>35</sup> For patients with no prescription claims of a sickle cell disease drug in the past 365 days, no ICD 10 diagnosis code indicating sickle cell disease submitted with their prescription claim, or no history of an ICD 10 diagnosis code indicating sickle cell disease in their member health profile who are identified through the prior authorization criteria as having sickle cell disease, step therapy criteria and post limit quantities will not apply.

The CDC Guideline for Prescribing Opioids for Chronic Pain states that for patients not already receiving opioids, clinicians should not initiate opioid treatment with extended-release opioids and should not prescribe extended-release opioids for intermittent use. Extended-release opioids should be reserved for severe, continuous pain and should be considered only for patients who have received immediate-release opioids daily for at least one week.<sup>31</sup>

Patients with chronic pain may need to be dosed on an around-the-clock basis rather than on an as needed basis. The American Pain Society (APS) Chronic Pain guideline states that short-acting opioids are probably safer for initial therapy since they have a shorter half-life and may be associated with a lower risk of inadvertent overdose. Proposed benefits of transitioning to long-acting opioids with around-the-clock dosing include more consistent control of pain, improved adherence, and lower risk of addiction or abuse. In patients on around-the-clock chronic opioid therapy with breakthrough pain, clinicians may consider as-needed opioids.<sup>34</sup>

Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.<sup>31</sup>

Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should consider history of overdose, history of substance use disorder, higher opioid dosages [ $\geq 50$  morphine milligram equivalents per day (MME/day)], or concurrent benzodiazepine use.<sup>31</sup>

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

≥90 MME/day.<sup>31</sup> The extended-release opioid drug initial quantity limits are set to encompass the usual/starting dosage and frequency range recommendations in labeling without exceeding a monthly quantity that corresponds to 90 MME/day. If the patient is requesting more than the initial quantity limit, then the system will reject with a message indicating that a prior authorization is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

The American Pain Society Opioid Treatment Guidelines state that a reasonable definition for high dose opioid therapy is >200 mg daily of oral morphine (or equivalent).<sup>34</sup> The extended-release opioid drug post limit quantities for approval are set to encompass the usual dosage and frequency range recommendations in labeling, or up to one additional dose per day above the initial quantity limit without exceeding a monthly quantity that corresponds to 200 MME/day (unless minimum FDA-labeled strength/dose/frequency exceeds a monthly quantity that corresponds to 200 MME/day) to promote optimization of pain management, safe and effective use, and to reduce misuse, abuse, and overdose.

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).<sup>6,12-15, 29-30</sup> The limit is set to reflect the use of methadone for the relief of pain. The limit is not intended for patients in detoxification and methadone maintenance programs. A separate initial quantity limit criteria exists for methadone concentrate and dispersible tablets since they are indicated for opioid dependence only.

Studies of opioid therapy for chronic pain that did not have a nonopioid control group have found that although many patients discontinue opioid therapy for chronic noncancer pain due to adverse effects or insufficient pain relief, there is weak evidence that patients who are able to continue opioid therapy for at least six months can experience clinically significant pain relief and insufficient evidence that function or quality of life improves. These findings suggest that it is very difficult for clinicians to predict whether benefits of opioids for chronic pain will outweigh risks of ongoing treatment for individual patients.<sup>31</sup> Therefore, patients who meet the prior authorization criteria for chronic pain will be approved for 6 months.

## PROCEDURES AND BILLING CODES

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

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## POLICY HISTORY

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