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

Belbuca, Butrans (buprenorphine)

Belbuca, Butrans (buprenorphine) 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, Butrans (buprenorphine) 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 (buprenorphine) are not indicated as an as-needed (prn) analgesic.

ConZip (tramadol hydrochloride extended-release)

ConZip (tramadol hydrochloride extended-release) capsules 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 (tramadol hydrochloride 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.

- ConZip (tramadol hydrochloride extended-release) capsules are not indicated as an as-needed (prn) analgesic.

Duragesic (fentanyl transdermal system)
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.

Fentanyl Transdermal System
Fentanyl transdermal system 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 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.

Hydromorphone Hydrochloride Extended-Release
Hydromorphone hydrochloride extended-release tablets are 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 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 (hydrocodone bitartrate extended-release) 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 (hydrocodone bitartrate 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.
- Hysingla ER (hydrocodone bitartrate extended-release) 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.

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 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 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 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.

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 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 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 (morphine extended-release) 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 MS Contin (morphine 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.
- MS Contin (morphine extended-release) is not indicated as an as-needed (prn) analgesic.

Nucynta ER (tapentadol extended-release)

Nucynta ER (tapentadol) 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.

OxyContin (oxycodone hydrochloride extended-release)

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 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 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 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 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 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 (hydrocodone bitartrate extended-release)

Zohydro ER (hydrocodone bitartrate) 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

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 ≤ 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.

These quantity limits should accumulate across all drugs of the same unit limit (i.e., drugs with 30 units accumulate together, drugs with 60 units accumulate together, etc).

		COLUMN A	**COLUMN B**	**COLUMN C**	**COLUMN D**
Drug/Strength	**Labeled Dosing**	**Initial 1 Month Limit*** **≤ 90 MME/day (per 25 days)**	**Initial 3 Month Limit*** **≤ 90 MME/day (per 75 days)**	**Post 1 Month Limit*** **≤ 200 MME/day**** **(per 25 days)**	**Post 3 Month Limit*** **≤ 200 MME/day**** **(per 75 days)**
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/ 3 months 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 (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	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 (20 MME/day)	90 caps/3 months 1 cap/day (20 MME/day)	60 caps/month 2 caps/day (40 MME/day)	180 caps/3 months 2 caps/day (40 MME/day)
ConZip 200 mg	qd, MAX 300 mg/day	0***	0***	30 caps/month 1 cap/day (40 MME/day)	90 caps/3 months 1 cap/day (40 MME/day)
ConZip 300 mg	qd, MAX 300 mg/day	0***	0***	30 caps/month 1 cap/day (60 MME/day)	90 caps/3 months 1 cap/day

					(60 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 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)
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 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 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)
Fentanyl transdermal 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)
Fentanyl transdermal 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)
Fentanyl transdermal 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)
Hydromorphone ER (generic Exalgo) 8 mg	qd	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)

Hydromorphone ER (generic Exalgo) 12 mg	qd	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)
Hydromorphone ER (generic Exalgo) 16 mg	qd	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)
Hydromorphone ER (generic Exalgo) 32 mg	qd	0***	0***	30 tabs/month 1 tab/day (160 MME/day)	90 tabs/3 months 1 tab/day (160 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)
Methadone 5 mg	q8-12h	90 tabs/month 3 tabs/day (70.5 MME/day)	270 tabs/3 months 3 tabs/day (70.5 MME/day)	120 tabs/month 4 tabs/day (94 MME/day)	360 tabs/3 months 4 tabs/day (94 MME/day)
Methadone (generic Dolophine) 5 mg	q8-12h	90 tabs/month 3 tabs/day (70.5 MME/day)	270 tabs/3 months 3 tabs/day (70.5 MME/day)	120 tabs/month 4 tabs/day (94 MME/day)	360 tabs/3 months 4 tabs/day (94 MME/day)
Methadone 10 mg	q8-12h	30 tabs/month 1 tab/day (47 MME/day)	90 tabs/3 months 1 tab/day (47 MME/day)	90 tabs/month 3 tabs/day (141 MME/day)	270 tabs/3 months 3 tabs/day (141 MME/day)
Methadone (generic Dolophine) 10 mg	q8-12h	30 tabs/month 1 tab/day (47 MME/day)	90 tabs/3 months 1 tab/day (47 MME/day)	90 tabs/month 3 tabs/day (141 MME/day)	270 tabs/3 months 3 tabs/day (141 MME/day)
Methadone 200 mg/20 mL injection	q8-12h	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)
Methadone 10 mg/mL Intensol soln	q8-12h	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 soln	q8-12h	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 soln	q8-12h	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	q24h, MAX 1600 mg/day	30 caps/month 1 cap/day	90 caps/3 months 1 cap/day	60 caps/month 2 caps/day	180 caps/3 months

		(30 MME/day)	(30 MME/day)	(60 MME/day)	2 caps/day (60 MME/day)
Morphine ER (generic 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)
Morphine ER (generic 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)
Morphine ER (generic 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)
Morphine ER (generic 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)
Morphine ER (generic Avinza) 120 mg	q24h, MAX 1600 mg/day	0***	0***	30 caps/month 1 cap/day (120 MME/day)	90 caps/3 months 1 cap/day (120 MME/day)
Morphine ER (generic 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)
Morphine ER (generic 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)
Morphine ER (generic 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)
Morphine ER (generic Kadian) 40 mg	q12-24h	60 caps/month 2 caps/day	180 caps/3 months 2 caps/day (80 MME/day)	90 caps/month 3 caps/day	270 caps/3 months

		(80 MME/day)		(120 MME/day)	3 caps/day (120 MME/day)
Morphine ER (generic 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)
Morphine ER (generic 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)
Morphine ER (generic 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)
Morphine ER (generic 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)
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)
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)
Oxymorphone ER (generic 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)
Oxymorphone ER (generic 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)
Oxymorphone ER (generic 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)
Oxymorphone ER (generic 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)
Oxymorphone ER (generic 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)
Oxymorphone ER (generic 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)

Oxymorphone ER (generic 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)
Tramadol ER 100 mg	qd, MAX 300 mg/day	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)
Tramadol ER 200 mg	qd, MAX 300 mg/day	0***	0***	30 tabs/month 1 tab/day (40 MME/day)	90 tabs/3 months 1 tab/day (40 MME/day)
Tramadol ER 300 mg	qd, MAX 300 mg/day	0***	0***	30 tabs/month 1 tab/day (60 MME/day)	90 tabs/3 months 1 tab/day (60 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 both quantity versus time and daily dose 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 in a patient who has been taking an opioid 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.[1-23]

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) Clinical Practice Guideline for Prescribing Opioids for Pain provides recommendations for clinicians providing pain care, including those prescribing opioids for outpatients aged ≥ 18 years. The recommendations do not apply to pain related to sickle cell disease or cancer or to patients receiving palliative or end-of-life care.[24] 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.[26] The NCCN Palliative Care pain management recommendation is to treat according to NCCN guidelines for adult cancer pain.[25] 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, 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.[28] 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, post limit quantities will not apply.

The CDC Clinical Practice Guideline for Prescribing Opioids for Pain states that clinicians should not treat acute pain with extended-release (ER)/long-acting (LA) opioids or initiate opioid treatment for subacute or chronic pain with ER/LA opioids, and clinicians should not prescribe ER/LA opioids for intermittent or as-needed use. ER/LA opioids should be reserved for severe, continuous pain and should be considered only for patients who have received certain dosages of immediate-release opioids daily (e.g., 60 mg daily of oral morphine, 30 mg daily of oral oxycodone, or equianalgesic dosages of other opioids) for at least 1 week.[24]

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.[27]

Risks of opioid use, including risk for overdose and overdose death, increase continuously with dosage, and there is no single dosage threshold below which risks are eliminated. When opioids are initiated for opioid-naïve patients with acute, subacute or chronic pain, clinicians should prescribe the lowest effective dosage. For patients not already taking opioids, the lowest effective dose can be determined using product labeling as a starting point with calibration as needed based on the severity of pain and other clinical factors such as renal or hepatic insufficiency. If opioids are continued for subacute or chronic pain, clinicians should use caution when prescribing opioids at any dosage and should generally avoid dosage increases when possible.[24]

Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risks for opioid-related harms and discuss risk with patients. Clinicians should reevaluate patients who are at higher risk for opioid use disorder or overdose (e.g., patients with depression or other mental conditions, a history of substance use disorder, a history of overdose, taking ≥ 50 MME/day, or taking other central nervous system depressants with opioids) more frequently than every 3 months. Clinicians should regularly screen all patients for these conditions, which can change during the course of treatment.[24]

Clinicians should evaluate benefits and risks with patients within 1 to 4 weeks of starting opioid therapy for subacute or chronic pain or of dose escalation. Clinicians should regularly reevaluate benefits and harms of continued opioid therapy with patients. Clinicians should regularly reassess all patients receiving long-term opioid therapy, with a suggested interval of every 3 months or more frequently for most patients. If benefits do not outweigh risks of continued opioid therapy, clinicians should optimize other therapies and work closely with patients to gradually taper opioids to lower dosages or if warranted based on the individual circumstances of the patient, appropriately taper and discontinue opioids.[24]

The CDC Clinical Practice Guideline for Prescribing Opioids for Pain recommends that when opioids are initiated for opioid-naïve patients, clinicians should prescribe the lowest effective dosage. If opioids are continued, clinicians should use caution when prescribing opioids at any dosage, should carefully evaluate individual benefits and risks

when considering increasing dosage, and should avoid increasing dosage above levels likely to yield diminishing returns in benefits relative to risks to patients. Many patients do not experience benefit in pain or function from increasing opioid dosages to ≥ 50 morphine milliequivalents per day (MME/day) but are exposed to progressive increases in risk as dosage increases. Opioid dosages of 50-90 MME/day were associated with a minimally greater improvement in mean pain intensity compared with dosages of < 50 MME/day. Few trials evaluated opioid dosages of ≥ 90 MME/day.[24] 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).[27] 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).[8-11,22,23] 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.

Unresolved acute pain or subacute pain (defined in the CDC clinical practice guideline as pain that has been present for 1-3 months) can evolve into chronic pain. Chronic pain typically lasts >3 months and can be the result of an underlying medical disease or conditional, injury, medical treatment, inflammation, or unknown cause. Clinical evidence reviews found insufficient evidence to determine long-term benefits of opioid therapy for chronic pain and found an increased risk for serious harms related to long-term opioid therapy that appears to be dose dependent. Compared with placebo, at short-term follow-up (1 to < 6 months) opioids were associated with small mean improvements in pain intensity. Some evidence indicates that improvement in pain is reduced with longer duration of opioid therapy. No placebo-controlled trial evaluated effectiveness of opioids at intermediate (6 to < 12 months) or long-term (≥ 12 months follow-up).[24] 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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