Introduction

Opioids are chemicals that bind to receptors in the brain or body. An opioid can be natural or synthetic. Opioid medications can be used to manage certain types of pain. Opioids are prescribed by and in consultation with a licensed healthcare professional. Examples of opioids are oxycodone, hydrocodone, and fentanyl.

This policy describes when you have to take certain drugs before an opioid can be prescribed. This policy also describes coverage criteria for quantities of some of the commonly prescribed opioid medications when prescribed above the allowable limit. Quantity limits in this policy are based on the maximum dose approved by the U.S. Food and Drug Administration. These dose limits are the upper range that clinical trials show to provide a balance between safety and effectiveness. Higher quantities may be approved based on adequate evidence from published peer reviewed clinical studies, comprehensive medical records history, and the criteria below. It is very easy to become dependent on opioids, and there is growing public concern about illegal drug use. Sale of prescription opioids pills as well as heroin is growing rapidly. For this reason, it is important to prescribe only as many opioid pills as a patient is expected to need. Properly disposing of unused pills is also important for safety. To learn more about this, ask your pharmacist or visit the FDA’s drug disposal page at https://www.fda.gov/forconsumers/consumerupdates/ucm101653.htm.

Note:  The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for
/providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Note: A copy of medical records history is required when submitting prior authorization requests for the drugs affected by this policy.

Note: This policy applies to all formulary types across all lines of business (see Definition of Terms below). As used in this policy, “Formulary” refers to the applicable formulary list specified in a member’s contract.

Note: Dispensing quantity limits are not intended to apply in circumstances where logistics may dictate otherwise. These circumstances include but are not limited to member vacation or business travel, disruption of normal prescription supply chains due to adverse weather events or other disasters and members living in remote areas where travel to the nearest pharmacy may sometimes be problematic.

Click on the links below to be directed to that section of the policy:

Short-Acting Opioid Step Therapy
Long-Acting Opioid Step Therapy
Long-Acting Opioid Quantity Limits

Zohydro ER® (hydrocodone ER) and hydrocodone bitartrate extended-release
OxyContin® (oxycodone ER)
Transmucosal Fentanyl Citrate Products

Short-Acting Opioid Step Therapy
A quantity sufficient for a 7-day supply will be covered without prior authorization. Additional quantities of BOTH brand and commercially available generic products for greater than a 7-day supply will require coverage review for opioid naïve patients. Opioid naïve is defined as not having history of any opioid within the past 130 days.

For a list of applicable drugs, see the table in the Related Information section below.
Short-Acting Opioid Step Therapy

Short-Acting Opioid, Greater Than 7-Day Supply: Medical Necessity

This policy does not apply to patients with cancer or those in a hospice program, end-of-life care, or palliative care.

Requests for more than 7 days of a short-acting opioid may be considered medically necessary in patients who meet ALL of the following criteria:

- At least one trial of a non-opioid medication (eg, nonsteroidal anti-inflammatory drugs [NSAIDs], acetaminophen) has provided an inadequate response, or non-opioid medications are inappropriate according to the prescribing clinician

AND

- The patient’s history of controlled substance prescriptions has been checked within the last 3 months using the state prescription drug monitoring program (PDMP), unless unavailable in the state

Note: Exceptions may be medically necessary for certain clinical situations on a case by case basis including but not limited to traumatic injury or surgeries with extended recovery time

Note: Documentation is required in the form of medical records for all reviews. All approvals are provided one time only and on a case by case basis.

Long-Acting Opioid Step Therapy

This step therapy is applicable to BOTH brand and commercially available generic products. This policy does not apply to patients with cancer or those in a hospice program, end-of-life care, or palliative care.

This step therapy does not apply to methadone, Dolophine® and Methadose™ when prescribed to treat opioid addiction (Opioid Use Disorder).

For a list of applicable drugs, see the table in the Related Information section below.

Long-Acting Opioid Therapy: Medical Necessity

Long-acting opioid may be considered medically necessary in patients with pain severe enough to require daily, around-the-clock, long-term opioid treatment where patients meet ALL of the following criteria:

- The patient has chronic pain and is not opioid naïve (opioid naïve is defined as not having history of any opioid within the past 130 days)

AND
**Long-Acting Opioid Step Therapy**

- Patient has a concurrent prescription or previous use of a short-acting opioid

**AND**

- Non-opioid therapies (eg, non-opioid medications [eg, nonsteroidal anti-inflammatory drugs (NSAIDs), tricyclic antidepressants, serotonin and norepinephrine reuptake inhibitors (SNRIs), anticonvulsants], exercise therapy, weight loss, cognitive behavioral therapy) have been optimized and are being used in conjunction with opioid therapy, or they have failed according to the prescribing clinician

**AND**

- Treatment plan (including goals for pain and function) is in place and reassessments (including pain levels and function) are scheduled at regular intervals according to the prescribing clinician

**AND**

- The patient’s history of controlled substance prescriptions has been checked within the last 3 months using the state prescription drug monitoring program (PDMP), unless unavailable in the state

**Note:** Documentation is required in the form of medical records for all reviews. Approvals are provided for one year in duration.

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**Long-Acting Opioid Quantity Limits**

**Coverage Guidelines for quantity limits that exceed national guidelines**

This policy does not apply to patients with cancer or those in a hospice program, end-of-life care, or palliative care.

**ALL of the following criteria must be met for short-term approval to be granted:**

- Patient is being seen by a board-certified pain specialist as defined by the American Board of Medical Specialties (ABMS)

**AND**

- Patient has had trials of 2 or more non-pharmacologic therapies, such as physical therapy, acupuncture, massage therapy, etc.

**AND**

- Patient has had trials of 3 or more non-opioid therapies, such as acetaminophen, NSAIDs, gaba-analogue, tricyclic antidepressants, SNRI’s, etc.

**AND**

- Patient and the doctor have a pain management contract in place

**AND**
Long-Acting Opioid Quantity Limits

Coverage Guidelines for quantity limits that exceed national guidelines

- Chart notes must include documentation that the (state-specific) Prescription Drug Monitoring Program was checked in the last 3 months

AND

- Patient participates in urine drug screening as per frequency documented in the provider’s chronic opioid therapy plan per medical records OR urine drug screening has been documented within the last 6 months

Note: Requests may be approved on a case by case basis for a maximum of 3 months to allow the provider time to reduce the dose to the allowed quantities (as described in the Long-Acting Opioid Quantity Limit table below).

Note: Documentation is required in the form of medical records for all reviews

Dispensing Quantity Limits

Quantity limits apply to BOTH brand and commercially available generic products.

The following drugs have quantity limits that are of ALL strengths combined in 30 days:

- Arymo® ER, Embeda® ER, Exalgo®, hydromorphone ER, Kadian®, morphine sulfate ER, Morphabond™ ER, MS Contin®, Nucynta® ER, Opana® ER, and oxymorphone ER

The following dispensing quantity limits are based on the maximum dose recommendations in the product’s FDA-approved labeling. This information is available for each product at the manufacturer’s web site or www.fda.gov. Opioid drugs with dispensing quantity limits are listed in the following table:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dosage / Strength</th>
<th>Quantity Limit Allowed Without Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arymo® ER (morphine sulfate ER)</td>
<td>15 mg, 30 mg, 60 mg ER tablet</td>
<td>Limit: 90 tablets per 30 days</td>
</tr>
<tr>
<td>Bunavail® (buprenorphine/naloxone)</td>
<td>2.1/0.3 mg, 4.2/0.7 mg buccal film</td>
<td>Limit: 90 films per fill</td>
</tr>
<tr>
<td>Bunavail® (buprenorphine/naloxone)</td>
<td>6.3/1mg mg buccal film</td>
<td>Limit: 60 films per fill</td>
</tr>
<tr>
<td>Embeda® (morphine sulfate ER/naltrexone HCl)</td>
<td>20mg/.08mg, 30mg/1.2mg, 50mg/2mg, 60mg/2.4mg,</td>
<td>Limit: 90 capsules per 30 days</td>
</tr>
<tr>
<td>Drug</td>
<td>Dosage / Strength</td>
<td>Quantity Limit Allowed Without Review</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>--------------------------------------------------------</td>
<td>-------------------------------------------------------------</td>
</tr>
<tr>
<td>Exalgo® (hydromorphone HCl ER)</td>
<td>80mg/3.2mg, 100mg/4mg ER capsule</td>
<td></td>
</tr>
<tr>
<td>Kadian® (morphine sulfate ER)</td>
<td>8 mg, 12 mg, 16 mg, 32 mg ER tablet</td>
<td>Limit: 60 tablets per 30 days</td>
</tr>
<tr>
<td>Morphabond™ ER (morphine sulfate ER)</td>
<td>10 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, 80 mg, 100 mg, 200 mg ER capsule</td>
<td>Limit: 90 capsules per 30 days</td>
</tr>
<tr>
<td>MS Contin® (morphine sulfate ER)</td>
<td>15 mg, 30 mg, 60 mg, 100 mg ER tablet</td>
<td>Limit: 60 tablets per 30 days</td>
</tr>
<tr>
<td>Nucynta® (tapentadol HCl)</td>
<td>50 mg, 75 mg, 100 mg tablet</td>
<td>Limit: 181 tablets per fill</td>
</tr>
<tr>
<td>Nucynta® ER (tapentadol HCl)</td>
<td>50 mg, 100 mg, 150 mg, 200 mg, 250 mg ER tablet</td>
<td>Limit: 60 tablets per 30 days</td>
</tr>
<tr>
<td>Opana® ER (oxymorphone HCl)</td>
<td>5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg tablet</td>
<td>Limit: 90 tablets per 30 days</td>
</tr>
<tr>
<td>OxyContin® (oxycodone HCl ER)</td>
<td>10 mg, 15 mg, 20 mg, 30 mg, 40 mg ER tablet</td>
<td>Limit: 90 tablets per 30 days</td>
</tr>
<tr>
<td>OxyContin® (oxycodone HCl ER)</td>
<td>60 mg, 80 mg ER tablet</td>
<td>Limit: 120 tablets per 30 days</td>
</tr>
<tr>
<td>Suboxone® (buprenorphine/naloxone)</td>
<td>12/3 mg film</td>
<td>Limit: 60 films per fill</td>
</tr>
<tr>
<td>Suboxone® (buprenorphine/naloxone)</td>
<td>2/0.5 mg, 4/1 mg, 8/2 mg film</td>
<td>Limit: 90 films per fill</td>
</tr>
<tr>
<td>Zubsolv® (buprenorphine/naloxone)</td>
<td>0.7/0.18 mg, 1.4/0.36 mg, 2.9/0.71 mg, 5.7/1.4 mg SL tablet</td>
<td>Limit: 90 tablets per fill</td>
</tr>
<tr>
<td>Zubsolv® (buprenorphine/naloxone)</td>
<td>8.6/2.1 mg SL tablet</td>
<td>Limit: 60 tablets per fill</td>
</tr>
<tr>
<td>Buprenorphine/naloxone (generic Suboxone®)</td>
<td>11.4/2.9 mg SL tablet</td>
<td>Limit: 30 tablets per fill</td>
</tr>
<tr>
<td>Buprenorphine/naloxone (generic Suboxone®)</td>
<td>12/3 mg film</td>
<td>Limit: 60 films per fill</td>
</tr>
<tr>
<td>Hydromorphone ER (generic Exalgo®)</td>
<td>8 mg, 12 mg, 16 mg, 32 mg tablet</td>
<td>Limit: 60 tablets per 30 days</td>
</tr>
<tr>
<td>Drug</td>
<td>Dosage / Strength</td>
<td>Quantity Limit Allowed Without Review</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>------------------------------------------------------------------------------------</td>
<td>----------------------------------------</td>
</tr>
<tr>
<td>Morphine sulfate ER (generic Kadian®)</td>
<td>10 mg, 20 mg, 30 mg, 50 mg, 60 mg, 80 mg, 100 mg, 200 mg ER capsule</td>
<td>Limit: 90 capsules per 30 days</td>
</tr>
<tr>
<td>Morphine sulfate ER (generic MS Contin®)</td>
<td>15 mg, 30 mg, 60 mg, 100 mg, 200 mg ER tablet</td>
<td>Limit: 120 tablets per 30 days</td>
</tr>
<tr>
<td>Morphine sulfate ER, 24 HR (generic Avinza®)</td>
<td>30 mg, 45 mg, 60 mg, 75 mg, 90 mg, 120 mg capsule</td>
<td>Limit: 60 capsules per 30 days</td>
</tr>
<tr>
<td>Oxycodone HCl ER (generic OxyContin®)</td>
<td>10 mg, 15 mg, 20 mg, 30 mg, 40 mg ER tablet</td>
<td>Limit: 90 tablets per 30 days</td>
</tr>
<tr>
<td>Oxycodone HCl ER (generic OxyContin®)</td>
<td>60 mg, 80 mg ER tablet</td>
<td>Limit: 120 tablets per 30 days</td>
</tr>
<tr>
<td>Oxymorphone ER (generic Opana® ER)</td>
<td>5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg ER tablet</td>
<td>Limit: 90 tablets per 30 days</td>
</tr>
</tbody>
</table>

**Long-Acting Opioid Medical Necessity Criteria**

**Zohydro ER® (hydrocodone bitartrate extended-release) and generic hydrocodone bitartrate extended-release**

*Zohydro ER® (hydrocodone bitartrate extended-release) and generic hydrocodone bitartrate extended-release may be considered medically necessary for the labeled indication of the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.*

**Zohydro ER® (hydrocodone bitartrate extended-release) and generic hydrocodone bitartrate extended-release may be covered when ALL of the following criteria are met:**

- Treatment of severe chronic pain that requires around the clock opioid pain management 
  **AND**
- Documented therapeutic failure of 2 long acting opioids (eg, fentanyl citrate, fentanyl transdermal, hydromorphone, morphine ER, OxyContin®) 
  **AND**
- Patient is not under the age of 19 years old 
  **AND**
- Quantity is not over 60 capsules per 30 days 
  **AND**
- In the event that a request is received that does not meet criteria for approval but is of a sufficiently high dose that would require tapering, a 3 month approval may be authorized to
Long-Acting Opioid Medical Necessity Criteria

allow the provider time to reduce the dose to the allowed quantities above. These requests may be approved on a case by case basis and are subject to a clinical review for medical necessity.

In the event where tapering cannot be achieved within a 3-months period, ALL of the following additional criteria must be met for approval to be granted:

- Patient is being seen by a board-certified pain specialist
- Patient and the doctor have a pain management contract in place
- Patient has had trials of other non-pharmacologic therapies, such as physical therapy, acupuncture, massage therapy, etc.
- Chart notes must include (state-specific) Prescription Drug Monitoring Program summary report (last 3 months)
- Patient participates in urine drug screening tests (last 3 months)

Note: First-time approvals will be covered for a period of 3 months (case-dependent). For continuation of coverage beyond the first 3 months new case review will be required. In addition, short term approvals may be given on a case by case basis when clinical rationale has been submitted by a provider indicating that a tapering dose is being attempted, and patient is expected to reach dosing of 120 Morphine Milligram Equivalent (MME) or less by the end of the 3 months. These requests are subject to a clinical review for medical necessity.

OxyContin® (oxycodone ER)

Extended-release oxycodone (OxyContin®) may be considered medically necessary for the labeled indication of the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

Extended release oxycodone (OxyContin®) may be covered when ALL of the following criteria are met:

- The quantity is not over three tablets per day of OxyContin 10 mg, 15 mg, 20 mg, 30 mg, 40 mg OR four tablets per day of OxyContin 60 mg and 80 mg.

AND
**Long-Acting Opioid Medical Necessity Criteria**

- In the event that a request is received that does not meet criteria for approval but is of a sufficiently high dose that would require tapering, a 3 month approval may be authorized to allow the provider time to reduce the dose to the allowed quantities above. These requests may be approved on a case by case basis and are subject to a clinical review for medical necessity.

**In the event where tapering cannot be achieved within a 3-months period ALL of the following criteria must be met for approval to be granted:**

- Medication is being prescribed by or in consultation with a board certified pain specialist as defined by the American Board of Medical Specialties (ABMS), **OR** by a licensed health professional with extensive training/experience in pain management.

  **AND**

- Patient and the doctor have a pain management contract in place

  **AND**

- Patient has had trials of other non-pharmacologic therapies, such as physical therapy, acupuncture, massage therapy, etc.

  **AND**

- Chart notes must include (state-specific) Prescription Drug Monitoring Program summary report (last 3 months)

  **AND**

- Patient participates in urine drug screening tests (last 3 months)

**Note:** First-time approvals will be covered for a period of 3 months (case-dependent). For continuation of coverage beyond the first 3 months new case review will be required. In addition, short term approvals may be given on a case by case basis when clinical rationale has been submitted by a provider indicating that a tapering dose is being attempted, and patient is expected to reach ≤120 Morphine Milligram Equivalent (MME) dosing by the end of the 3 months. These requests are subject to a clinical review for medical necessity.

**Note:** Quantity limit requests that are the result of a lower strength tablet being used in multiples that could be achieved with a higher dose tablet (ie, three 20mg tablets versus one 60mg tablet) will not be approved. In certain circumstances, an approval may be given based on clinical rationale submitted and would be subject to a review for medical necessity.
## Long-Acting Opioid Medical Necessity Criteria

### Transmucosal fentanyl citrate products

Transmucosal fentanyl citrate products (e.g., Abstral®, Actiq®, Fentora™, Lazanda®, Onsolis™, Subsys®) may be considered medically necessary for the treatment of breakthrough cancer pain in adult patients with compromised oral intake or absorption.

## Coding

N/A

## Related Information

### Short-Acting Opioid, Greater Than 7-Day Supply: Drugs

**Acetaminophen with codeine: Oral suspension, tablet**
- Tylenol® with codeine

**Acetaminophen/caffeine/dihydrocodeine: Capsule, tablet**
- Trezix™

**Aspirin/caffeine/dihydrocodeine: Capsule**
- Synalgos®-DC

**Belladonna and Opium: Suppository**

**Benzhydrocodone/acetaminophen**
- Apadaz™
- Benzhydrocodone/acetaminophen

**Buprenorphine: Injection**
- Buprenex®

**Butalbital/acetaminophen/caffeine/codeine: Capsule**
- Fioricet® with Codeine

**Butorphanol: Injection, nasal spray**
- Butorphanol Tartrate Novaplus

**Carisoprodol/aspirin/codeine: Tablet**

**Codeine sulfate: Tablet**

**Codeine/butalbital/aspirin/caffeine: Capsule**
- Fiorinal® with Codeine
### Short-Acting Opioid, Greater Than 7-Day Supply: Drugs

**Hydrocodone/acetaminophen: Oral elixir, oral solution, oral tablet**
- Hycet®
- Lor cet®️️, Lor cet HD®, Lor cet Plus®️️
- Lortab®, Lortab®️️ Elixir
- Norco®️️
- Ver dro cet®️️
- Vicodin®, Vicodin ES®, Vicodin HP®️️
- Xodol®️️

**Hydrocodone/ibuprofen: Tablet**
- Ib udone®️️
- Reprexain™️️
- Vicopro fen®️️
- Xylon™️️

**Hydromorphone: Injection, oral solution, rectal suppository, tablet**
- Dilaudid®, Simplist Dilaudid®️️

**Ibuprofen/oxycodone: Tablet**

**Levorphanol: Tablet**

**Meperidine: Injection, oral solution, oral syrup, tablet**
- Demerol®, Meperitab™️️

**Morphine: Injection, oral solution, rectal suppository, tablet**
- Duramorph®️️
- Infumorph®️️
- Mitigo®️️

**Nalbuphine: Injection**
- Nalbuphine HCl Novaplus

**Oxycodone: Capsule, injection, oral concentrate, oral solution, tablet**
- Oxaydo®️️
- Oxy IR®️️
- Roxi codone®️️
- Roxyb o nd™️️

**Oxycodone/acetaminophen: Tablet, solution**
- Endoc et®️️
- Nalocet®️️
- Oxycodone HCl-Acetaminophen AvPak™️️
- Percocet®️️
- Primlev™️️

**Oxycodone/asp irin: Tablet**
- Percodan®️️

**Oxymorphone: Tablet**
Short-Acting Opioid, Greater Than 7-Day Supply: Drugs

- Opana®
- Pentazocine lactate: Injection
- Talwin®
- Pentazocine/naloxone: Tablet
- Tapentadol: Tablet
- Nucynta®
- Tramadol: Oral suspension, tablet
  - FusePaq Synapryn™
  - Ultram®
- Tramadol/acetaminophen: Tablet
  - Ultrace®

Long-Acting Opioid Therapy: Drugs

- Buprenorphine: Buccal film, injection, intradermal implant, transdermal patch
  - Belbuca®
  - Buprenex®
  - Buprenorphine patch
  - Butrans®
- Fentanyl: Transdermal patch
  - Duragesic®
  - Fentanyl Transdermal System Novaplus
  - Ionsys®
- Hydrocodone ER: Capsule, tablet
  - Hysingla® ER
  - Zohydro® ER
- Hydromorphone ER: Tablet
  - Exalgo®
- Methadone: Injection, oral solution, tablet, tablet for suspension
  - Diskets® Dispersible
  - Dolophine® HCl
  - Methadol HCl Intensol™
  - Methadose™
- Morphine sulfate ER: Capsule, tablet
  - Arymo® ER
  - Kadian®
  - Morphabond ER™
  - MS Contin®
- Morphine sulfate and naltrexone ER: Capsule
### Long-Acting Opioid Therapy: Drugs

- Embeda®
- Oxycodone HCl ER: Tablet
  - OxyContin® ER
- Oxycodone ER: Capsule
  - Xtampza® ER
- Oxymorphone ER: Tablet
  - Opana® ER
- Tapentadol ER: Tablet
  - Nucynta® ER
- Tramadol ER: Capsule, tablet
  - Conzip™
  - Ultram® ER

### Benefit Application

This policy is managed through the Pharmacy Benefit. It applies to all pharmacy benefit contracts that include Pharmacy Prior Authorization Edits.

### Definition of Terms

**Formulary:** A formulary is a list of drugs approved by the Pharmacy and Therapeutics Committee (P&T) for routine use. A well-designed formulary should provide adequate drug selection to meet the treatment needs of most patients; however, there will always be exceptional cases where a non-formulary drug may be the best therapeutic choice.

**Formulary drug:** A formulary drug (also known as a preferred drug) is a drug that is on the formulary list. Drugs that are not on the list are referred to as non-formulary drugs.

**Label:** Product label refers to the FDA approved prescribing information that is available for every legend drug approved for use in the U.S. The label includes indications, contraindications, recommended dosing, warnings, precautions, side effects, drug interactions, and information on safety in pregnancy and other special populations. The drug’s pharmacology, pharmacokinetics, and available dosage forms are also provided. The current format also includes a summary of the pivotal clinical trials that were submitted to FDA in support of the New Drug Application.

This prescribing information is included as a package insert with the product and is available on the manufacturer’s web site.
**Quantity limits:** A quantity limit is the maximum amount of a medication that may be dispensed during a given calendar period or at one prescription fill without an exception request. Dispensing of a larger quantity may be approved, based on individual case review. A specified larger quantity may be approved when patient-specific circumstances require it, or when published clinical evidence supports a higher dose protocol.

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**Evidence Review**

**Background**

Opioid analgesics are commonly used for the management of pain. An estimated 20% of patients presenting to physician offices with pain symptoms or pain-related diagnoses (including acute and chronic pain) unrelated to cancer receive an opioid prescription.

Short-acting opioids are indicated for the management of pain severe enough to require an opioid analgesic. The objective of this quantity limit is to restrict the initial days’ supply of short-acting opioids to seven days, thus decreasing the quantity dispensed to align with current guidelines and prevent stockpiling and/or misuse.

The currently available long-acting (due to either an extended-release formulation or a long half-life [i.e., methadone]) opioids are buprenorphine, hydrocodone, hydromorphone, methadone, morphine sulfate, oxycodone, oxymorphone, tapentadol, and tramadol. All of the long-acting 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. Extended-release opioid dosage forms offer a long duration of effect, reduce severity of end-of-dose pain, and allow many patients to sleep through the night. Long-acting products should be prescribed with an immediate-release dosage form, to be used as needed for breakthrough pain.

**Description**

Analgesics are used to treat a wide variety of pain syndromes. Traditionally, these have been classified in three groups: acute pain, chronic cancer pain and chronic pain in non-cancer patients. Each requires a different approach. In acute pain the goal is to keep the patient comfortable while avoiding respiratory depression and minimizing the potential of opioid
dependence. Oncology patients are managed to achieve the best functional balance of analgesia versus sedation. No maximum dose limits exist in this setting, while chronic non-cancer pain should be managed with regimens that combine drugs from different pharmacologic classes to minimize opioid use, eg, antidepressants, NSAIDs or acetaminophen, muscle relaxants, and anticonvulsants.

**Opioid Abuse**

Abuse of prescription opioid products is a growing concern. The 2006 National Survey on Drug Use and Health (NSDUH) found 4.7 million people used a prescription opioid for non-medical purposes in the month prior to the survey. More than 2 million per year are considered new illicit users of prescription opioids, a 5-fold increase from the 1980s. For people older than age 12 in 2007, more began illicitly using opioids than marijuana, cocaine, or any other illegal drug. In addition to abuse of opioids, prescriptions of opioids for pain are also increasing. From 1992 to 2002 prescriptions for opioids increased 154% while the US population increased 13%. Along with this increase in legitimate and illicit use of opioids has come an increase in ER visits and deaths due to opioids use.

- The public health surveillance system, Drug Abuse Warning System (DAWN), last published data on drug related emergency visits from 2008 and found the largest number of ER visits occurred with oxycodone combinations (105,214) followed by hydrocodone combinations (89,051), and then methadone (63,629). These numbers have increased dramatically from 2004 with a 152% increase for oxycodone, 123% with hydrocodone, and 73% with methadone (all p<0.05). The rationale for the ER visit (drug abuse, side effects etc.) was not included.

- An analysis of serious events from the FDA’s adverse event reporting system found oxycodone (with 5,548 reports) was suspected in the largest number of deaths and serious nonfatal outcomes. The cause of the adverse event (drug abuse, side effects etc.) was not included.

- An analysis of deaths among Medicaid enrollees from overdose in Washington state from 2004–2007 found methadone was involved in the most deaths (64%), followed by oxycodone (22.9%), and hydrocodone (13.9%).

- Adverse events related to methadone have increased 1800% from 1997 to 2004, with a 390% increase in fatalities during the same period. Most methadone deaths appear to be the result of accidental exposures, although more data are needed.
While it is clear that use of and adverse events caused by opioids are increasing, the data do not differentiate between events due to increased legitimate prescribing for pain and those due to illicit use. Additionally, as the number of total exposures to each drug is unknown, it is difficult to determine the risk associated with each drug due to lack of a meaningful denominator.

In 2010, the Washington State Legislature passed a statute requiring professional boards to draft regulations managing high-dose opioid use, clearly recognized as a serious threat to public health.

**Extended-Release Oxycodone**

The purpose of the OxyContin® quantity limit is fourfold:

- Reduce unnecessarily large quantities from being dispensed, thereby decreasing the likelihood of unnecessary tablets remaining in medicine cabinets where relatives and other visitors to the home could pilfer them.

- Remind prescribers to select a larger tablet size when increasing the dose, rather than ordering two tablets to be taken at one time.

- Serve as a warning signal in cases where a patient may be using part of the prescription non-medically, or may be diverting pills for use by others for whom they were not prescribed.

OxyContin® is normally dosed every 12 hours and is designed to be administered as 2 tablets per day. In individuals with more-rapid-than-normal clearance of oxycodone, or other unusual clinical circumstances, it is likely that 3 per day would be required. By setting the limit at 3, the Plan allows for flexibility on the part of practitioners and their patients. OxyContin is available in tablet sizes of 10, 15, 20, 30, 40, 60, and 80 mg. When the 80mg tablet size is reached, the patient should be receiving 160mg/day. For cancer patients needing to go beyond this dose, the 4 tablet limit allows a further escalation to 320mg/day before approval of a quantity override would be needed. Exception for medical necessity will be routinely given when the patient is being treated for cancer pain and has reached the maximum dosage achievable with 4 tablets per day.
Transmucosal Fentanyl

Transmucosal fentanyl agents are potent analgesics approved for the treatment of breakthrough pain in opioid-treated and tolerant cancer patients. There is no fully published randomized controlled evidence for use of these products for non-cancer pain at this time.

Availability of longer-term safety/tolerability data with Fentora® is limited. Because life-threatening respiratory depression could occur at any dose in opioid non-tolerant patients, Fentora® and Actiq® are contraindicated in the management of acute or postoperative pain, and for use in opioid non-tolerant patients. A unique adverse event issue identified with use of Fentora® is application site reactions, including ulceration. Risk is difficult to define, due to the limited number of patients and duration of exposure to this formulation in clinical trials. This side effect has the potential to alter the formulation’s absorption characteristics and may increase risk for serious side effects in some patients. To ensure safety, a cautious approach to use of either transmucosal fentanyl product is warranted.

Management of chronic severe pain in cancer patients requires the effective use of long-acting opioids, supplemented with limited doses of a short-acting opioid (rescue medication). Excessive doses of rescue medication usually indicate suboptimal pain control. This problem can be alleviated by increasing the fraction of the total daily opioid dose given as long-acting opioid.

2019 Updates

A literature search was conducted from October 1, 2018, to November 1, 2019, and no new evidence was found that would change this policy. Review of FDA labeling updates for long-acting opioids in this policy found no new evidence that would change the quantity limits listed on this policy.

References


9. SAMHSA. Results from the 2006 National Survey on Drug Use and Health: national findings. Rockville, MD: Substance Abuse and Mental Health Services Administration; 2007b.


27. MS Contin® tablets [prescribing information]. Stamford, CT: Purdue Frederick; April 2014.
29. OxyContin® tablets [prescribing information]. Stamford, CT: Purdue Pharma LP; August 2015.
<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/13/11</td>
<td>Replace Policy – Policy updated with additional approval parameters and dosing limitation for OxyContin.</td>
</tr>
<tr>
<td>11/13/12</td>
<td>Replace policy. A literature search did not indicate the need to update the criteria in this policy.</td>
</tr>
<tr>
<td>03/15/13</td>
<td>Update Related Policies. Add 5.01.542.</td>
</tr>
<tr>
<td>07/08/13</td>
<td>Minor Update – Clarification was added to the policy that it is managed through the member’s pharmacy benefit; this is now listed in the header and within the coding section.</td>
</tr>
<tr>
<td>10/14/13</td>
<td>Replace policy. Medically necessary policy statement for OxyContin updated with new FDA labeling and stricter FDA indication wording.</td>
</tr>
<tr>
<td>04/14/14</td>
<td>Annual review. Policy updated with extended-release hydrocodone (Zohydro ER®) as medically necessary for the labeled indication of the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.</td>
</tr>
<tr>
<td>12/01/14</td>
<td>Update Related Policies. Add 5.01.546.</td>
</tr>
<tr>
<td>10/13/15</td>
<td>Annual Review. Policy statements for Cox-II (Celebrex) removed as this medication no longer requires prior authorization. Title updated, removed “Non-Opioid” as this only pertained to Celebrex.</td>
</tr>
<tr>
<td>02/09/16</td>
<td>Annual Review. Criteria for Zohydro ER removed from Policy Guidelines: concomitant therapy with CNS depressants or inhibitors of CYP3A4; no history of COPD; and, no current or recent head injury.</td>
</tr>
<tr>
<td>05/01/16</td>
<td>Interim update, approved April 12, 2016. Additional criteria for OxyContin® and Zohydro® ER quantity limit are included.</td>
</tr>
<tr>
<td>01/01/17</td>
<td>Interim Update, approved December 13, 2016. Quantity limit criteria for transmucosal fentanyl products (TIRFs) has been removed.</td>
</tr>
<tr>
<td>06/01/17</td>
<td>Annual Review, approved May 23, 2017. Policy moved into new format. Created introduction summary and removed the word “preferred” from the coverage criteria for Zohydro ER. Medical records requirement statement is now included in the policy.</td>
</tr>
<tr>
<td>10/01/18</td>
<td>Annual Review, approved September 11, 2018. Significant revision of the policy; added contents of policy 5.01.579 and 5.01.583 to this policy. Title changed from “Opioid Analgesics” to “Management of Opioid Therapy”.</td>
</tr>
<tr>
<td>05/01/19</td>
<td>Interim Review, approved April 2, 2019. Added Apadaz™ (benzhydrocodone and acetaminophen) and benzhydrocodone/acetaminophen to short-acting opioid therapy. Added buprenorphine patch to long-acting opioid therapy.</td>
</tr>
<tr>
<td>01/01/20</td>
<td>Annual Review, approved December 10, 2019. No changes to policy statement.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
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</tr>
<tr>
<td>03/01/20</td>
<td>Interim Review, approved February 20, 2020. For the Long-Acting Opioid Step Therapy criteria added an exception for methadone, Dolophine® and Methadose™ when prescribed to treat opioid addiction. Added generic hydrocodone bitartrate extended-release to policy.</td>
</tr>
</tbody>
</table>

**Disclaimer**: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2020 Premera All Rights Reserved.

**Scope**: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
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  • Written information in other formats (large print, audio, accessible electronic formats, other formats)
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  • Qualified interpreters
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Toll free 855-332-4535, Fax 425-918-5952. TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at

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المعاقية التي تقدم المحصول عليها من خلال Premera Blue Cross. هذه المعلومات تشمل:
• داخل النطاق: 800-722-1471 (TTY: 800-842-5357) 037338 (07-2016)

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Italiano (Italian):