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PHARMACY POLICY – 5.01.529

Management of Opioid Therapy

Effective Date:	Apr. 1, 2023	RELATED MEDICAL POLICIES:
Last Revised:	Mar. 14, 2023	None
Replaces:	5.01.579, 5.01.583	

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

Clicking this icon returns you to the hyperlinks menu above.

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, fentanyl, and morphine.

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. For this reason, it is important to prescribe only as many opioid pills as a individual 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

A quantity sufficient for a 7-day supply will be covered for individuals ≥ 18 years of age 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 individuals. Opioid naïve is defined as not having history of any opioid within the past 130 days.

A quantity sufficient for a 3-day supply will be covered for individuals < 18 years of age without prior authorization. Additional quantities of **BOTH brand and commercially available generic products** for greater than a 3-day supply will require coverage review for

Short-Acting Opioid Step Therapy

opioid naïve individuals. 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, Greater Than 7-Day Supply: Medical Necessity

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

Requests for more than 7 days of a short-acting opioid for individuals ≥ 18 years of age may be considered medically necessary in individuals who meet ALL of the following criteria:

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

AND

- The individual'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.

Short-Acting Opioid, Greater Than 3-Day Supply: Medical Necessity

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

Requests for more than 3 days of a short-acting opioid for individuals < 18 years of age may be considered medically necessary in individuals who meet ALL of the following criteria:

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

AND

Short-Acting Opioid Step Therapy

- The individual'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 individuals with cancer, sickle cell disease, 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

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

- The individual 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

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

AND

- Non-opioid therapies (e.g., non-opioid medications [e.g., 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

Long-Acting Opioid Step Therapy

- 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 individual'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.

Long-Acting Opioid Quantity Limits

Coverage Guidelines for Quantity Limits that Exceed National Guidelines

This policy does not apply to individuals with cancer, sickle cell disease 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:

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

AND

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

AND

- Individual has had trials of 3 or more non-opioid therapies, such as acetaminophen, NSAIDs, gaba-analogues, tricyclic antidepressants, SNRI's, etc.

AND

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

AND

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

AND

- Individual 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

Long-Acting Opioid Quantity Limits
Coverage Guidelines for Quantity Limits that Exceed National Guidelines
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:

- Hydromorphone ER, Kadian®, morphine sulfate ER, Morphabond™ ER, MS Contin®, Nucynta® 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:

Drug	Dosage / Strength	Quantity Limit Allowed Without Review
Bunavail® (buprenorphine/naloxone)	2.1/0.3 mg, 4.2/0.7 mg buccal film	Limit: 90 films per fill
Bunavail® (buprenorphine/naloxone)	6.3/1 mg buccal film	Limit: 60 films per fill
Hydromorphone HCl ER	8 mg, 12 mg, 16 mg, 32 mg ER tablet	Limit: 60 tablets per 30 days
Kadian® (morphine sulfate ER)	10 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, 80 mg, 100 mg, 200 mg ER capsule	Limit: 90 capsules per 30 days
Morphabond™ ER (morphine sulfate ER)	15 mg, 30 mg, 60 mg, 100 mg ER tablet	Limit: 60 tablets per 30 days
MS Contin® (morphine sulfate ER)	15 mg, 30 mg, 60 mg, 100 mg, 200 mg ER tablet	Limit: 120 tablets per 30 days
Nucynta® (tapentadol HCl)	50 mg, 75 mg, 100 mg tablet	Limit: 181 tablets per fill

Drug	Dosage / Strength	Quantity Limit Allowed Without Review
Nucynta® ER (tapentadol HCl)	50 mg, 100 mg, 150 mg, 200 mg, 250 mg ER tablet	Limit: 60 tablets per 30 days
Oxymorphone HCl ER	5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg tablet	Limit: 90 tablets per 30 days
OxyContin® (oxycodone HCl ER)	10mg, 15 mg, 20 mg, 30 mg, 40 mg ER tablet	Limit: 90 tablets per 30 days
OxyContin® (oxycodone HCl ER)	60 mg, 80 mg ER tablet	Limit: 120 tablets per 30 days
Suboxone® (buprenorphine/naloxone)	12/3 mg film	Limit: 60 films per fill
Suboxone® (buprenorphine/naloxone)	2/0.5 mg, 4/1 mg, 8/2 mg film 2/0.5 mg, 8/2 mg SL tablet	Limit: 90 films per fill
Zubsolv® (buprenorphine/naloxone)	0.7/0.18 mg, 1.4/0.36 mg, 2.9/0.71 mg, 5.7/1.4 mg SL tablet	Limit: 90 tablets per fill
Zubsolv® (buprenorphine/naloxone)	8.6/2.1 mg SL tablet	Limit: 60 tablets per fill
Zubsolv® (buprenorphine/naloxone)	11.4/2.9 mg SL tablet	Limit: 30 tablets per fill
Buprenorphine/naloxone (generic Suboxone®)	12/3 mg film	Limit: 60 films per fill
Buprenorphine/naloxone (generic Suboxone®)	2/0.5 mg, 4/1 mg, 8/2 mg film 2/0.5 mg, 8/2 mg SL tablet	Limit: 90 films per fill
Hydromorphone ER (generic Exalgo®)	8 mg, 12 mg, 16 mg, 32 mg tablet	Limit: 60 tablets per 30 days
Morphine sulfate ER (generic Kadian®)	10 mg, 20 mg, 30 mg, 50 mg, 60 mg, 80 mg, 100 mg, 200 mg ER capsule	Limit: 90 capsules per 30 days
Morphine sulfate ER (generic MS Contin®)	15 mg, 30 mg, 60 mg, 100 mg, 200 mg ER tablet	Limit: 120 tablets per 30 days
Morphine sulfate ER, 24 HR (generic Avinza®)	30 mg, 45 mg, 60 mg, 75 mg, 90 mg, 120 mg capsule	Limit: 60 capsules per 30 days
Oxycodone HCl ER (generic OxyContin®)	10 mg, 15 mg, 20 mg, 30 mg, 40 mg ER tablet	Limit: 90 tablets per 30 days
Oxycodone HCl ER (generic OxyContin®)	60 mg, 80 mg ER tablet	Limit: 120 tablets per 30 days
Oxymorphone ER (generic Opana® ER)	5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg ER tablet	Limit: 90 tablets per 30 days

Drug	Dosage / Strength	Quantity Limit Allowed Without Review
Hydrocodone ER (generic Hysingla® ER)	20 mg, 30 mg, 40 mg, 60 mg, 80 mg, 100 mg, and 120 mg	Limit: 60 tablets per 30 days
Hydorocodone ER (generic Zohydro® ER)	10 mg, 15 mg, 20 mg, 30 mg, 40 mg, and 50 mg	Limit: 60 capsules per 30 days
Hysingla® ER (hydorocodone bitartrate ER)	20 mg, 30 mg, 40 mg, 60 mg, 80 mg, 100 mg, and 120 mg	Limit: 60 tablets per 30 days
Zohydro® ER (hydrocodone bitartrate ER)	10 mg, 15 mg, 20 mg, 30 mg, 40 mg, and 50 mg	Limit: 60 capsules per 30 days

Transmucosal Fentanyl Citrate Products

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

Coding

N/A

Related Information

Short-Acting Opioid Therapy Drugs

Acetaminophen with codeine: Oral suspension, tablet

- Tylenol® with codeine

Acetaminophen/caffeine/dihydrocodeine: Capsule, tablet

- Trezix™

Aspirin/caffeine/dihydrocodeine: Capsule

Belladonna and Opium: Suppository

Benzhydrocodone/acetaminophen

- Apadaz™
- Benzhydrocodone/acetaminophen

Short-Acting Opioid Therapy Drugs

Buprenorphine: Injection

- Buprenex®

Butalbital/acetaminophen/caffeine/codeine: Capsule

- Fioricet® with Codeine

Butorphanol: Injection, nasal spray

Carisoprodol/aspirin/codeine: Tablet

Codeine sulfate: Tablet

Codeine/butalbital/aspirin/caffeine: Capsule

- Fiorinal® with Codeine

Hydrocodone/acetaminophen: Oral elixir, oral solution, oral tablet

- Lorcet®, Lorcet HD®, Lorcet Plus®
- Lortab®, Lortab® Elixir
- Norco®
- Vicodin®, Vicodin HP®

Hydrocodone/ibuprofen: Tablet

- Ibudone®

Hydromorphone: Injection, oral solution, rectal suppository, tablet

- Dilaudid®

Ibuprofen/oxycodone: Tablet

Levorphanol: Tablet

Meperidine: Injection, oral solution, oral syrup, tablet

- Demerol®

Morphine: Injection, oral solution, rectal suppository, tablet

- Duramorph®
- Infumorph®
- Mitigo®

Nalbuphine: Injection

Oxycodone: Capsule, injection, oral concentrate, oral solution, tablet

- Oxaydo®
- Roxicodone®
- Roxybond™

Oxycodone/acetaminophen: Tablet, solution

- Endocet®
- Nalocet®
- Percocet®
- Primlev™
- Prolate™

Oxycodone/aspirin: Tablet

Oxymorphone: Tablet

Short-Acting Opioid Therapy Drugs

- Opana®

Pentazocine lactate: Injection

- Talwin®

Pentazocine/naloxone: Tablet

Tapentadol: Tablet

- Nucynta®

Tramadol: Oral suspension, tablet

- Qdolo®
- Ultram®

Tramadol/acetaminophen: Tablet

- Ultracet®

Tramadol/celecoxib: Tablet

- Seglentis®

Long-Acting Opioid Therapy Drugs

Buprenorphine: Buccal film, injection, intradermal implant, transdermal patch

- Belbuca®
- Buprenex®
- Buprenorphine patch
- Butrans®

Fentanyl: Transdermal patch

- Duragesic®

Hydrocodone ER: Capsule, tablet

- Hysingla® ER
- Zohydro® ER

Methadone: Injection, oral solution, tablet, tablet for suspension

- Diskets® Dispersible
- Dolophine® HCl
- Methadone HCl Intensol™
- Methadose™

Morphine sulfate ER: Capsule, tablet

- Kadian® ER
- Morphabond ER™
- MS Contin®

Oxycodone HCl ER: Tablet

- OxyContin® ER

Oxycodone ER: Capsule

- Xtampza® ER

Long-Acting Opioid Therapy Drugs
Oxymorphone ER: Tablet **Tapentadol ER: Tablet** • Nucynta® ER **Tramadol ER: Capsule, tablet** • Conzip™

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 individuals; 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 individual-specific circumstances require it, or when published clinical evidence supports a higher dose protocol.

Evidence Review

Background

Opioid analgesics are commonly used for the management of pain. An estimated 20% of individuals 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 individuals 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 individuals. Each requires a different approach. In acute pain the goal is to keep the individual comfortable while avoiding respiratory depression and minimizing the potential of opioid dependence. Oncology individuals 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 (e.g., 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 U.S. 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 is cases where a individual 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 individuals. OxyContin is available in tablet sizes of 10, 15, 20, 30, 40, 60, and 80 mg. When the 80mg tablet size is reached, the individual should be receiving 160mg/day. For cancer individuals 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 individual 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 individuals. 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 individuals,

Fentora® and Actiq® are contraindicated in the management of acute or postoperative pain, and for use in opioid non-tolerant individuals. 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 individuals 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 individuals. To ensure safety, a cautious approach to use of either transmucosal fentanyl product is warranted.

Management of chronic severe pain in cancer individuals 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.

2021 Updates

A literature search was conducted from July 1, 2020, to June 30, 2021, and no new evidence was found that would change this policy.

2022 Updates

Updated the short-acting opioid step-therapy requirement to limit to a 3-day supply for individuals < 18 years of age. Conducted an extensive review of product availability and removed from the short-acting opioid table and the long-acting opioid table many products that are no longer available. Also added a couple new products, Qdolo® (tramadol oral solution) and Seglentis® (tramadol and celecoxib), to the short-acting opioid table.

2023 Updates

Removed OxyContin® ER and Zohydro® ER criteria and added OxyContin® ER and Zohydro® ER into the long-acting opioid step therapy criteria. Added generic Hysingla® ER, Hysingla® ER, generic Zohydro® ER, and Zohydro® ER to the long-acting opioid quantity limits criteria.

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24. Kadian® capsules [prescribing information]. Parsippany, NJ: Actavis Pharma, Inc.; Revised March 2021.

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26. OxyContin® tablets [prescribing information]. Stamford, CT: Purdue Pharma LP; Revised October 2021.

27. Zohydro® ER extended-release capsules [prescribing information]. San Diego, CA: Zogenix, Inc; Revised March 2021.

28. Hysingla™ ER extended-release tablets [prescribing information]. Stamford, CT: Purdue Pharma L.P.; Revised March 2021.

29. Xtampza ER™ extended-release capsules [prescribing information]. Cincinnati, OH: Patheon Pharmaceuticals; Revised March 2021.

30. Conzip® extended-release capsules [prescribing information]. Sayreville, NJ: Vertical Pharmaceuticals, LLC; Revised September 2021.

31. Dolophine [prescribing information]. Eatontown, NJ: West-Ward Pharmaceuticals Corp.; Revised June 2021.

32. Belbuca™ buccal film [prescribing information]. Raleigh, NC: BioDelivery Sciences International, Inc.; Revised June 2022.

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History

Date	Comments
02/08/11	Add to Prescription Drug Section - New Policy.
12/13/11	Replace Policy – Policy updated with additional approval parameters and dosing limitation for OxyContin.
11/13/12	Replace policy. A literature search did not indicate the need to update the criteria in this policy.
03/15/13	Update Related Policies. Add 5.01.542.
07/08/13	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.
10/14/13	Replace policy. Medically necessary policy statement for OxyContin updated with new FDA labeling and stricter FDA indication wording.
04/14/14	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.
12/01/14	Update Related Policies. Add 5.01.546.
10/13/15	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.
02/09/16	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.
05/01/16	Interim update, approved April 12, 2016. Additional criteria for OxyContin® and Zohydro® ER quantity limit are included.
01/01/17	Interim Update, approved December 13, 2016. Quantity limit criteria for transmucosal fentanyl products (TIRFs) has been removed.
06/01/17	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.

Date	Comments
10/01/18	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”.
05/01/19	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.
07/01/19	Interim Review, approved June 4, 2019. Removed Sublocade and Probuphine under long-acting opioid therapy.
01/01/20	Annual Review, approved December 10, 2019. No changes to policy statement.
03/01/20	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.
04/01/20	Interim Review, approved March 19, 2020. Added sickle cell disease as a condition for when coverage criteria do not apply.
09/01/20	Annual Review, approved August 20, 2020. No changes to policy statement. Added Prolate (oxycodone and acetaminophen) to the short-acting opioid table.
09/01/21	Annual Review, approved August 3, 2021. No changes to policy statement.
10/01/22	Annual Review, approved September 13, 2022. Updated the short-acting opioid step-therapy requirement to limit to a 3-day supply for individuals < 18 years of age. Removed Onsolis from list of transmucosal fentanyl citrate products as no longer available. Removed Synalgos-DC, Hycet, Verdrocet, Vicodin ES, Xodol, Reprexain, Vicoprofen, Xylon, Simplist Dilaudid, Meperitab, Oxy IR, Percodan, and FusePaq Synapryn from the short-acting opioid table as products are no longer available. Added Qdolo (tramadol oral solution) and Seglentis (tramadol and celecoxib) to the short-acting opioid table. Removed Embeda ER, Fentanyl Transdermal System Novaplus, Ionsys, Exalgo, Arymo ER, Opana ER, and Ultram ER from the long-acting opioid table as products are no longer available. Changed the wording from "patient" to "individual" throughout the policy for standardization.
04/01/23	Annual Review, approved March 14, 2023. Removed OxyContin ER and Zohydro ER criteria and added OxyContin ER and Zohydro ER into the long-acting opioid step therapy criteria. Added generic Hysingla ER, Hysingla ER, generic Zohydro ER, and Zohydro ER to the long-acting opioid quantity limits criteria.

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.

Discrimination is Against the Law

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Washington residents: You can also file a civil rights complaint with the Washington State Office of the Insurance Commissioner, electronically through the Office of the Insurance Commissioner Complaint Portal available at https://www.insurance.wa.gov/file-complaint-or-check-your-complaint-status, or by phone at 800-562-6900, 360-586-0241 (TDD). Complaint forms are available at https://fortress.wa.gov/oic/onlineservices/cc/pub/complaintinformation.aspx.

Alaska residents: Contact the Alaska Division of Insurance via email at insurance@alaska.gov, or by phone at 907-269-7900 or 1-800-INSURAK (in-state, outside Anchorage).

Language Assistance

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 800-722-1471 (TTY: 711).

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 800-722-1471 (TTY: 711).

注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 800-722-1471 (TTY：711）。

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 800-722-1471 (TTY: 711).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 800-722-1471 (TTY: 711) 번으로 전화해 주십시오.

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 800-722-1471 (телетайп: 711).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 800-722-1471 (TTY: 711).

MO LOU SILAFIA: Afai e te tautala Gagana fa'a Sāmoa, o loo iai auaunaga fesoasoan, e fai fua e leai se totogi, mo oe, Telefoni mai: 800-722-1471 (TTY: 711).

ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 800-722-1471 (TTY: 711).

注意事項：日本語を話される場合、無料の言語支援をご利用いただけます。800-722-1471 （TTY:711）まで、お電話にてご連絡ください。

PAKDAAR: Nu saritaem ti Ilocano, ti serbisyo para ti baddang ti lengguahe nga awanan bayadna, ket sidadaan para kenyam. Awagan ti 800-722-1471 (TTY: 711).

УВАГА! Якщо ви розмовляєте українською мовою, ви можете звернутися до безкоштовної служби мовної підтримки. Телефонуйте за номером 800-722-1471 (телетайп: 711).

ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតឈ្នួល គឺអាចមានសំរាប់បំរើអ្នក។ ចូរ ទូរស័ព្ទ 800-722-1471 (TTY: 711)។

ማስታወሻ: የሚናገሩት ቋንቋ ኣማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጀተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 800-722-1471 (መስማት ለተሳናቸው፡ 711).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 800-722-1471 (TTY: 711).

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 800-722-1471 (رقم هاتف الصم والبكم: 711).

ਧਿਆਨ ਦਿਓ: ਜੇ ਤੁਸੀਂ ਪੰਜਾਬੀ ਬੋਲਦੇ ਹੋ, ਤਾਂ ਭਾਸ਼ਾ ਵਿੱਚ ਸਹਾਇਤਾ ਸੇਵਾ ਤੁਹਾਡੇ ਲਈ ਮੁਫਤ ਉਪਲਬਧ ਹੈ। 800-722-1471 (TTY: 711) 'ਤੇ ਕਾਲ ਕਰੋ।

เรียน: ถ้าคุณพูดภาษาไทยคุณสามารถใช้บริการช่วยเหลือทางภาษาได้ฟรี โทร 800-722-1471 (TTY: 711).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 800-722-1471 (TTY: 711).

UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 800-722-1471 (TTY: 711).

ATANSYON: Si w pale Kreyòl Ayisyen, gen sèvis èd pou lang ki disponib gratis pou ou. Rele 800-722-1471 (TTY: 711).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 800-722-1471 (ATS : 711).

ATENÇÃO: Se fala português, encontram-se disponíveis serviços linguísticos, grátis. Ligue para 800-722-1471 (TTY: 711).

ATTENZIONE: In caso la lingua parlata sia l'italiano, sono disponibili servizi di assistenza linguistica gratuiti. Chiamare il numero 800-722-1471 (TTY: 711).

توجه: اگر به زبان فارسی گفتگو می کنید، تسهیلات زبانی بصورت رایگان برای شما فراهم می باشد. با 800-722-1471 (TTY: 711) تماس بگیرید.