

PHARMACY COVERAGE GUIDELINE

Analgesics, Narcotic Long-Acting:
BELBUCA (buprenorphine) 12H buccal film
BUTRANS® (buprenorphine) weekly extended-release patch
Buprenorphine weekly extended-release patch
DURAGESIC® (fentanyl) 72H patch
Fentanyl (fentanyl) 72H patch
Hydrocodone 12H extended-release capsule
Hydrocodone 24H extended-release tablet
Hydromorphone ER (hydromorphone) 24H tablet
HYSINGLA® ER (hydrocodone) 24H tablet
Morphine Sulfate extended-release capsule
Morphine Sulfate extended-release tablet
MS CONTIN® (morphine sulfate) extended-release tablet
NUCYNTA® ER (tapentadol) 12H tablet
OXYCODONE ER 12H tablet
OXYCONTIN® (oxycodone) 12H extended-release tablet
Oxymorphone ER (oxymorphone) 12H tablet
XTAMPZA® ER (oxycodone) 12H capsule
ZOHYDRO® ER (hydrocodone) 12H capsule

This Pharmacy Coverage Guideline (PCG):

- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively “Service”) is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider’s judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member’s benefit plan; and
- Is subject to change as new information becomes available.

Scope

- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance

- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The “Criteria” section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member’s benefit plan.
- The “Description” section describes the Service.
- The “Definition” section defines certain words, terms or items within the policy and may include tables and charts.
- The “Resources” section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**

PHARMACY COVERAGE GUIDELINE

Analgesics, Narcotic Long-Acting

- Information about medications that require precertification is available at www.azblue.com/pharmacy. You must fully complete the [request form](#) and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.
-

Criteria:

- **Criteria for initial therapy: Analgesics, Narcotic Long-Acting** is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:
 1. Individual is consistent with product label
 2. A confirmed diagnosis of **ONE** of the following:
 - a. Cancer related pain
 - b. Palliative care with life expectancy less than 6 months
 - c. Chronic pain severe enough to require daily, around-the-clock, long-term opioid treatment
 3. Coordination of care will be performed between different prescribers for **ALL** controlled substances
 4. The requested extended-release opiate is not prescribed as an as-needed (prn) analgesic
 5. Individual is taking an immediate release opioid for at least 4 weeks or is switching from an alternative extended-release opiate
 6. **For non-cancer pain: For morphine equivalent dosing (MED) greater than 90 MED/day:**
 - a. For extended-release doses >90 MED/day, prescriber is a pain management specialist or in consultation with a pain specialist.
 - b. A dosing schedule to bring individual to a lower dosage of MED ≤90 MED/day (titration schedule required)
 7. **For non-cancer pain: A treatment plan, including:**
 - a. Pain intensity (scales or ratings)
 - b. Functional status (physical and psychosocial)
 - c. Patient's goal of therapy (level of pain acceptable and/or functional status)
 - d. Current non-pharmacological treatment
 8. **For non-cancer pain: Physician-patient pain management contract must be provided**
 9. **For non-cancer pain: Documentation must be included for random urine or blood tests at least twice a year**
 10. **For non-cancer pain: Documentation of PDMP reviewed by the prescriber every time a prescription for controlled substance is provided**
 11. **For non-cancer pain: One pharmacy (and another 24-hour closest pharmacy) must be selected for all the controlled substances prescription services (limitation may vary by specific member's benefit plan*)**

PHARMACY COVERAGE GUIDELINE

Analgesics, Narcotic Long-Acting

12. **For non-cancer pain:** Individual has been evaluated and must **not** have an active addiction to illicit substances or prescription drugs or a history of risky, harmful, non-medical or inappropriate use of these and other substances that might be unhealthy, hazardous or a problem (i.e.; multiple providers, multiple pharmacy or multiple controlled substances)
13. There is **NO** concomitant use with benzodiazepines such as clonazepam, lorazepam, diazepam etc. **OR** there is a treatment plan to taper use and to coordinate care among all prescribers
14. **For non-cancer pain: NOT** being used in combination with any other long-acting opioid therapy
15. **For non-cancer pain: NOT** being used for the treatment of opioid dependence
16. **For non-cancer pain:** Failure, contraindication per FDA label, or intolerance to at least **ONE** other alternative treatment options for **Belbuca buccal film, hydromorphone 24H ER tab, Hysingla 24H ER tab, Nucynta 12H ER tab, Oxycontin 12H ER tab, Oxycodone 12H ER tab, Oxymorphone 12H ER tab, Zohydro 12H ER cap, hydrocodone 12H ER cap** such as:
 - a. Butrans (brand or generic) weekly patch
 - b. Fentanyl transdermal 72H patch
 - c. Morphine Extended Release (brand or generic)
 - d. Xtampza ER capsule
17. **Request for a branded long-acting narcotic agent:** Individual has failure, contraindication per FDA label, or intolerance to its equivalent generic
18. There are **NO** FDA-label contraindications, such as:
 - a. Significant respiratory depression
 - b. Acute or severe bronchial asthma
 - c. Known or suspected gastrointestinal obstruction, including paralytic ileus
 - d. Hypersensitivity to any components of the formulation

Initial approval duration:

- For all approvals, recommend prescribing Naloxone to accompany the long-acting opioid
- Approve at the requested dosage for 6 months for pain not related to cancer
- Approve at the requested dosage for 12 months for pain related to cancer or for palliative care
- For non-cancer pain, one pharmacy (and another 24-hour closest pharmacy) must be selected for all the controlled substances prescription services (limitation may vary by specific member's benefit plan*)

- **Criteria for continuation of coverage (renewal request):** Analgesics, Narcotic Long-Acting is considered **medically necessary** and will be approved when **ALL** the following criteria are met (**samples are not considered for continuation of therapy**):

1. Individual's pain is controlled
2. **Request for continuation of a branded long-acting narcotic agent:** Individual has failure, contraindication per FDA label, or intolerance to its equivalent generic

PHARMACY COVERAGE GUIDELINE

Analgesics, Narcotic Long-Acting

3. There is documentation that coordination of care is being performed between different prescribers for **ALL** controlled substances
4. The condition has not progressed or worsened while on therapy and has not developed severe side effects like:
 - a. Apnea, dyspnea, epistaxis, hemoptysis, hyperventilation, hypoxia, upper respiratory infection etc.
 - b. Confusion/speech disturbance
 - c. Dehydration
 - d. Atrial fibrillation/arrhythmia/chest pain
 - e. Ascites
5. **For non-cancer pain:** A **treatment plan**, including:
 - a. Pain intensity (scales or ratings)
 - b. Functional status (physical and psychosocial)
 - c. Patient's goal of therapy (level of pain acceptable and/or functional status)
 - d. Current non-pharmacological treatment
6. **For non-cancer pain:** Physician-patient **pain management contract** must be provided
7. **For non-cancer pain:** Documentation must be included for **random urine or blood tests at least twice a year**
8. **For non-cancer pain:** Documentation of **PDMP reviewed** by the prescriber every time a prescription for controlled substance is provided
9. **For non-cancer pain:** **One pharmacy (and another 24-hour closest pharmacy)** must be selected for all the controlled substances prescription services (limitation may vary by specific member's benefit plan*)
10. **For non-cancer pain:** Individual has been evaluated and must **not** have an active addiction to illicit substances or prescription drugs or a history of risky, harmful, non-medical or inappropriate use of these and other substances that might be unhealthy, hazardous or a problem (i.e.; multiple providers, multiple pharmacy or multiple controlled substances)
11. **For non-cancer pain:** **NOT** being used in combination with any other long-acting opioid therapy
12. **For non-cancer pain:** **NOT** being used for the treatment of opioid dependence
13. There is **NO** concomitant use with benzodiazepines such as clonazepam, lorazepam, diazepam etc. **OR** there is a treatment plan to taper use and coordinate care among all prescribers

Renewal duration:

- For all approvals, recommend prescribing Naloxone to accompany the long-acting opioid.
- Approve at the requested dosage for 12 months for pain not related to cancer
- Approve at the requested dosage for 12 months for pain related to cancer
- For non-cancer pain, one pharmacy (and another 24-hour closest pharmacy) must be selected for all the controlled substances prescription services (limitation may vary by specific member's benefit plan*)

*For Qualified Health Plans (QHP) for Individuals/Families and Small Groups:

PHARMACY COVERAGE GUIDELINE

Analgesics, Narcotic Long-Acting

"**Narcotics Designated Network Program**" is a program that requires certain members taking narcotic medications to obtain prescriptions for all covered narcotic medications from one designated eligible physician or other provider and to obtain all covered narcotic medications from one network pharmacy designated by BCBSAZ and/or the PBM.

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:
 1. **Off-Label Use of Non-Cancer Medications**
 2. **Off-Label Use of Cancer Medications**
-

Description:

All opioids are similarly effective for pain relief as determined by years of clinical experience, systematic reviews, and clinical practice guidelines. There is no evidence that supports superiority of one product (brand or generic) over another product (brand or generic). There is also no evidence to support superiority of a long acting opioid agent over a short acting opioid agent. There is no evidence in efficacy between scheduled dosing of a sustained release opioid over as needed dosing of an immediate release opioid. There is no reliable evidence that any one opioid is safer than another, including abuse-deterrent formulations, long-acting opioids compared to short-acting opioids, Schedule 3 Controlled Substances compared to Schedule 2 Controlled Substances (Fentanyl, Morphine, others), or use of partial- versus pure opioid agonists. Clinical guidelines recognize the use of long-acting opioids for management of chronic pain in specific circumstances but do not recommend one medication or dosage form.

Evidence on long-term opioid therapy for chronic pain is very limited but suggests an increased risk of serious harms that are dose dependent. Long-term opioids for chronic pain are associated with increased risk of abuse, overdose, fracture, and myocardial infarction versus not currently being prescribed opioids. All long-acting opioid analgesics have a boxed warning for addiction, abuse, misuse, life-threatening respiratory depression, accidental exposure, and neonatal opioid withdrawal syndrome.

Definitions:

CDC Recommendations for Opioid Prescribing for Chronic Pain:

A. Determining when to initiate or continue opioids for chronic pain

1. Opioids are not first-line or routine therapy for chronic pain
2. Establish and measure goals for pain and function
3. Discuss benefits and risks and availability of non-opioid therapies with patient

B. Opioid selection, dosage, duration, follow-up, and discontinuation

1. Use immediate-release opioids when starting
2. Start low and go slow-Use caution at any dose and avoid increasing to high dosages
3. When opioids are needed for acute pain, prescribe no more than needed
 - Do NOT prescribe ER/LA opioids for acute pain

PHARMACY COVERAGE GUIDELINE

Analgesics, Narcotic Long-Acting

4. Follow-up and re-evaluate risk of harm; reduce dose or taper and discontinue if opioids cause harm or are not helping

C. Assessing risk and addressing harms of opioid use

1. Evaluate risk factors for opioid-related harms
2. Check CSPMP for high dosages and prescriptions from other providers at the beginning of the treatment and at least quarterly while on the opioid treatment
3. Use urine drug testing to identify prescribed substances and undisclosed use
4. Avoid concurrent benzodiazepine and opioid prescribing
5. Arrange treatment for opioid use disorder if needed

Prescriber Education:

A. Guidelines for Prescribing Opioids for Chronic Pain

https://www.cdc.gov/drugoverdose/pdf/TurnTheTide_PocketGuide-a.pdf

http://www.agencymeddirectors.wa.gov/Files/FY16-288SummaryAMDGOpioidGuideline_FINAL.pdf

https://www.cdc.gov/drugoverdose/pdf/Guidelines_Factsheet-a.pdf

B. Checklist for prescribing opioids for chronic pain

https://www.cdc.gov/drugoverdose/pdf/PDO_Checklist-a.pdf

C. Tapering Opioids for Chronic Pain

https://www.cdc.gov/drugoverdose/pdf/Clinical_Pocket_Guide_Tapering-a.pdf

D. Non-Opioid Treatments

https://www.cdc.gov/drugoverdose/pdf/nonopioid_treatments-a.pdf

E. Assessing Benefits and Harms of Opioid

https://www.cdc.gov/drugoverdose/pdf/Assessing_Benefits_Harms_of_Opioid_Therapy-a.pdf

F. Calculating Total Daily Dose of Opioids for Safer Dosage

https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf

G. Checking Controlled Substances Prescription Monitoring Program (CSPMP)

<https://arizona.pmpaware.net/login>

<https://pharmacympm.az.gov/>

H. Educational Webinar Series for Prescribers

<https://www.cdc.gov/drugoverdose/pdf/COCA-webinar-series-allslides-a.pdf>

<https://www.cdc.gov/drugoverdose/prescribing/trainings.html>

<http://www.coperems.org/>

I. CDC Guideline for Prescribing Opioids for Chronic Pain

<https://www.cdc.gov/drugoverdose/prescribing/clinical-tools.html>

J. Washington State Opioid Taper Plan Calculator

www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf

PHARMACY COVERAGE GUIDELINE

Analgesics, Narcotic Long-Acting

K. Tapering Long-Term Opioid Therapy in Chronic Non-cancer Pain
[www.mayoclinicproceedings.org/article/S0025-6196\(15\)00303-1/fulltext](http://www.mayoclinicproceedings.org/article/S0025-6196(15)00303-1/fulltext)

L. UpToDate
<https://www.uptodate-com>

Opioid Risk Assessment Tool:

Score each that applies	Female	Male
Family history of substance abuse		
Alcohol	1	3
Illegal drugs	2	3
Rx drugs	4	4
Personal history of substance abuse		
Alcohol	3	3
Illegal drugs	4	4
Rx drugs	5	5
Age between 16-45 years	1	1
History of preadolescent sexual abuse	3	0
Psychological disorders		
ADD, OCD, Bipolar, Schizophrenia	2	2
Depression	1	1
Total score		
Assessment of risk		
Low risk for abuse	≤ 3	
Moderate risk for abuse	4-7	
High risk for abuse	≥ 8	
Definitions of risk		
Low = unlikely to abuse		
Moderate = as likely will as will not abuse		
High = likely to abuse		

Resources:

- Belbuca (buprenorphine hydrochloride) 12-hour soluble film product Information, revised by manufacturer BioDelivery Sciences International, Inc 03-2021. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed February 19, 2022.
- Butrans (buprenorphine) extended release weekly patch product Information, revised by manufacturer Purdue Pharma LP. 03-2021. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed February 19, 2022.
- Buprenorphine extended release weekly patch product Information, revised by manufacturer Apotex. 03-2021. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed February 19, 2022
- Duragesic (fentanyl system). Product Information, revised by manufacturer Janssen Pharmaceuticals, Inc 10/2019, at DailyMed <http://dailymed.nlm.nih.gov>. Accessed October 21, 2020. Discontinued 04-01-2019.
- Fentanyl 72-hour patch product information, revised by Mylan Pharmaceutical, Inc. 03-2021. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed February 19, 2022.

ORIGINAL EFFECTIVE DATE: 09/01/2020 | ARCHIVE DATE: | LAST REVIEW DATE: 05/19/2022 | LAST CRITERIA REVISION DATE: 08/18/2022

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.

PHARMACY COVERAGE GUIDELINE

Analgesics, Narcotic Long-Acting

Exalgo (hydromorphone hydrochloride). Product Information, revised by manufacturer SpecGx LLC 6/2020, at DailyMed <http://dailymed.nlm.nih.gov>. Accessed 10/21/20. Discontinued 02-12-2019.

Hydromorphone hydrochloride 24-hour extended release tablet product information, revised by Padagis US LLC 11-2021. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed February 19, 2022.

Hysingla ER (hydrocodone bitartrate) 24-hour extended release tablet product Information, revised by manufacturer Purdue Pharma LP 03-2021. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed February 19, 2022.

Hydrocodone bitartrate 24-hour extended release tablet product Information, revised by manufacturer Alvogen, Inc. 05-2021. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed February 19, 2022.

MS Contin (morphine sulfate) 8-12-hour extended release tablet product Information, revised by manufacturer Rhodes Pharmaceuticals L.P. 03-2021. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed February 19, 2022.

Morphine sulfate 8-12-hour extended-release tablet product information, revised by Actavis Pharma, Inc. 11-2021. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed February 19, 2022.

Morphine sulfate 12-24-hour extended release capsule product information, revised by Actavis Pharma, Inc. 03-2021. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed February 19, 2022.

Nucynta ER (tapentadol hydrochloride) 12-hour extended-release tablet product Information, revised by manufacturer Collegium Pharmaceutical, Inc 03-2021. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed February 19, 2022.

Oxycontin (oxycodone hydrochloride) 12-hour extended release tablet product Information, revised by manufacturer Purdue Pharma LP. 10-2021. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed February 20, 2022.

Oxycodone hydrochloride 12-hour extended release tablet product Information, revised by manufacturer Teva Pharmaceuticals USA, INC., LLC 10-2021. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed February 20, 2022.

Xtampza ER (oxycodone) 12-hour extended release capsule product Information, revised by manufacturer Collegium Pharmaceutical, Inc. 02-2021. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed February 20, 2022.

Oxymorphone 12-hour extended release tablet product information, revised by Amneal Pharmaceuticals of New York, LLC. 12-2021. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed February 19, 2022.

Zohydro (hydrocodone bitartrate). Product Information, revised by manufacturer Zogenix, Inc. 8/2014 at DailyMed <https://dailymed.nlm.nih.gov>. Accessed October 21, 2020. Discontinued 07-15-2021.

Hydrocodone bitartrate 12-hour extended release capsule product information, revised by Alvogen, Inc. 03-2021. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed February 19, 2022.

Tauben D, Stacey BR. Approach to the management of chronic non-cancer pain in adults. In: UpToDate, Fishman S, Crowley M (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Topic last updated November 20, 2020. Accessed February 18, 2022.

Tauben D, Stacey BR. Pharmacologic management of chronic non-cancer pain in adults. In: UpToDate, Fishman S, Crowley M (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Topic last updated December 16, 2021. Accessed February 18, 2022.

Rosenquist R. Use of opioids in the management of chronic non-cancer pain. In: UpToDate, Aronson MD, Fishman S, Crowley M (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Topic last updated January 21, 2022. Accessed February 18, 2022.

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.