

PHARMACY COVERAGE GUIDELINES

SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: LAST REVIEW DATE: LAST CRITERIA REVISION DATE: 9/01/2020 5/20/2021 5/20/2021

ARCHIVE DATE:

Analgesics, Narcotic Long-Acting:

BELBUCA (buprenorphine hydrochloride) buccal film

BUTRANS® (buprenorphine) patch, extended-release

DURAGESIC® and Fentanyl (fentanyl transdermal) patch

EMBEDA® (morphine sulfate and naltrexone hydrochloride) extended-release capsule

EXALGO® ER and Hydromorphone ER (hydromorphone hydrochloride) tablet

HYSINGLA® ER (hydrocodone bitartrate) tablet

Morphine Sulfate (extended-release) capsule

MS CONTIN® and Morphine Sulfate (morphine sulfate extended-release) tablet

NUCYNTA® ER (tapentadol) tablet

OXYCONTIN® and OXYCODONE ER (oxycodone hydrochloride) tablet

Oxymorphone ER (oxymorphone hydrochloride) tablet

XTAMPZA® ER (oxycodone hydrochloride) capsule

ZOHYDRO® ER (hydrocodone bitartrate) capsule

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "<u>Description</u>" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "<u>Criteria</u>" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the <u>request form</u> in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to <u>Pharmacyprecert@azblue.com</u>. **Incomplete forms or forms without the chart notes will be returned.**

Criteria:

- <u>Criteria for initial therapy</u>: Analgesics, Narcotic Long-Acting is considered medically necessary and will be approved when ALL of the following criteria are met:
 - 1. Individual is 16 years of age or older
 - 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) analogesic
 - 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.
 - 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



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- 8. For non-cancer pain: Physician-patient pain management contract must be provided
- 9. **For non-cancer pain**: Documentation must be included for <u>random urine or blood tests</u> at least twice a year
- 10. **For non-cancer pain**: Documentation of <u>PDMP reviewed</u> 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*)

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)

- 12. There is **NO** concomitant use with benzodiazepines-ex. clonazepam, lorazepam, diazepam etc. **OR** there is a treatment plan to taper use and to coordinate care among all prescribers
- 13. For non-cancer pain: NOT being used in combination with any other long-acting opioid therapy
- 14. For non-cancer pain: NOT being used for the treatment of opioid dependence
- 15. For non-cancer pain: Failure, contraindication, or intolerance to at least <u>ONE</u> other alternative treatment options for Hysingla ER, Nucynta ER, Zohydro ER, Exalgo, hydromorphone ER, Oxymorphone ER, Oxycontin, Oxycodone ER, Belbuca, like:
 - a. Morphine Extended Release (brand or generic)
 - b. Embeda ER capsule
 - c. Xtampza ER
 - d. Butrans
 - e. Fentanyl transdermal
- 16. There are **NO** contraindications.
 - a. Contraindications include:
 - i. Significant respiratory depression
 - ii. Acute or severe bronchial asthma
 - iii. Known or suspected gastrointestinal obstruction, including paralytic ileus
 - iv. Hypersensitivity to any components of the formulation

Initial approval duration:

- For all approvals, recommend prescribing Naloxone to accompany the long-acting opioid.
- Will be approved at the requested dosage for 6 months for pain not related to cancer
- Will be approved at the requested dosage for 12 months for pain related to cancer
- Will be approved at the requested dosage for 12 months for palliative care

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- 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*)
- <u>Criteria for continuation of coverage (renewal request)</u>: Analgesics, Narcotic Long-Acting is considered *medically necessary* and will be approved when ALL of the following criteria are met:
 - 1. Individual's pain is controlled
 - There is documentation that coordination of care is being performed between different prescribers for ALL controlled substances
 - The condition has not progressed or worsened while on therapy and no development of 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
 - 4. 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
 - 5. For non-cancer pain: Physician-patient pain management contract must be provided
 - 6. **For non-cancer pain**: Documentation must be included for <u>random urine or blood tests</u> at least twice a year
 - 7. **For non-cancer pain**: Documentation of <u>PDMP reviewed</u> by the prescriber every time a prescription for controlled substance is provided
 - 8. 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 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)
 - 10. For non-cancer pain: NOT being used in combination with any other long-acting opioid therapy
 - 11. For non-cancer pain: NOT being used for the treatment of opioid dependence



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12. There is **NO** concomitant use with benzodiazepines-ex. 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.
- Will be approved at the requested dosage for 12 months for pain not related to cancer
- Will be approved 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:

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- verses 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

[&]quot;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.

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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
- 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 <u>CSPMP</u> 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:

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

- Checklist for prescribing opioids for chronic pain
 - https://www.cdc.gov/drugoverdose/pdf/PDO_Checklist-a.pdf
- Tapering Opioids for Chronic Pain
 - https://www.cdc.gov/drugoverdose/pdf/Clinical_Pocket_Guide_Tapering-a.pdf
- Non-Opioid Treatments
 - https://www.cdc.gov/drugoverdose/pdf/nonopioid_treatments-a.pdf
- Assessing Benefits and Harms of Opioid
 - https://www.cdc.gov/drugoverdose/pdf/Assessing_Benefits_Harms_of_Opioid_Therapy-a.pdf
- Calculating Total Daily Dose of Opioids for Safer Dosage
 - https://www.cdc.gov/drugoverdose/pdf/calculating total daily dose-a.pdf
- Checking Controlled Substances Prescription Monitoring Program (CSPMP)
 - https://arizona.pmpaware.net/login
 - https://pharmacypmp.az.gov/
- 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/

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- CDC Guideline for Prescribing Opioids for Chronic Pain https://www.cdc.gov/drugoverdose/prescribing/clinical-tools.html
- Washington State Opioid Taper Plan Calculator www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf
- Tapering Long-Term Opioid Therapy in Chronic Non-cancer Pain www.mayoclinicproceedings.org/article/S0025-6196(15)00303-1/fulltext
- UpToDate

https://www-uptodate-com.mwu.idm.oclc.org/contents/overview-of-the-treatment-of-chronic-non-cancer-pain?source=search_result&search=non-cancer%20pain&selectedTitle=1~150

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	<u><</u> 3	
Moderate risk for abuse	4-7	
High risk for abuse	<u>≥</u> 8	
Definitions of risk	·	
Low = unlikely to abuse		
Moderate = as likely will as will not abuse		
High = likely to abuse		



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Resources:

Belbuca (buprenorphine hydrochloride) Product Information, revised by manufacturer BioDelivery Sciences International, Inc 07/2020, at DailyMed https://dailymed.nlm.nih.gov. Accessed 10/21/20.

Butrans (buprenorphine). Product Information, revised by manufacturer Purdue Pharma LP 10/2019, at DailyMed https://dailymed.nlm.nih.gov. Accessed 10/21/20.

Duragesic (fentanyl system). Product Information, revised by manufacturer Janssen Pharmaceuticals, Inc 10/2019, at DailyMed https://dailymed.nlm.nih.gov. Accessed 10/21/20.

Exalgo (hydromorphone hydrochloride). Product Information, revised by manufacturer SpecGx LLC 6/2020, at DailyMed https://dailymed.nlm.nih.gov. Accessed 10/21/20.

Hysingla ER (hydrocodone bitartrate). Product Information, revised by manufacturer Purdue Pharma LP 10/2019, at DailyMed https://dailymed.nlm.nih.gov. Accessed 10/21/20.

MS Contin (morphine sulfate). Product Information, revised by manufacturer Rhodes Pharmaceuticals L.P. 10/2019, at DailyMed https://dailymed.nlm.nih.gov. Accessed 10/21/20.

Nucynta (tapentadol hydrochloride). Product Information, revised by manufacturer Collegium Pharmaceutical, Inc 10/2019, at DailyMed https://dailymed.nlm.nih.gov. Accessed 10/21/20.

Oxycontin (oxycodone hydrochloride). Product Information, revised by manufacturer Purdue Pharma LP 9/2020, at DailyMed https://dailymed.nlm.nih.gov. Accessed 10/27/20.

Oxymorphone Hydrochloride. Product Information, revised by manufacturer Aurolife Pharma, LLC 8/2020, at DailyMed https://dailymed.nlm.nih.gov. Accessed 10/21/20.

Xtampza ER (oxycodone). Product Information, revised by manufacturer Collegium Pharmaceutical, Inc, 10/2019 at DailyMed https://dailymed.nlm.nih.gov. Accessed 10/21/20.

Zohydro (hydrocodone bitartrate). Product Information, revised by manufacturer Zogenix, Inc. 8/2014 at DailyMed https://dailymed.nlm.nih.gov. Accessed 10/21/20.

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.