



PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 9/21/17
LAST REVIEW DATE: 8/15/19
LAST CRITERIA REVISION DATE: 8/15/19
ARCHIVE DATE:

BELBUCA™ (buprenorphine) buccal film

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 “Description” 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 “Criteria” 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 request form 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 Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

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Criteria:

- **Criteria for initial therapy:** Belbuca (buprenorphine) 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:
 - cancer related pain
 - pain severe enough to require daily, around-the-clock, long-term opioid treatment
 3. Tried, failed or has contraindication to at least **2 other alternative** treatment options like:
 - Morphine sustained release (brand or generic)
 - Embeda ER capsule
 - Nucynta ER tablets
 - Oxycondone ER tablets (brand or generic)
 - Fentanyl transdermal patches
 4. Coordination of care will be performed between different prescribers for **ALL** controlled substances
 5. Tried, failed or has contraindication to **Butrans (buprenorphine)** transdermal system
 6. **For non-cancer pain:** For **morphine equivalent dosing (MED) greater than 180mg/day:**
 - A dosing schedule to bring individual to a lower dosage of MED less than 180mg/day (titration schedule required)
 7. **For non-cancer pain:** A **treatment plan**, including:
 - Pain intensity (scales or ratings)
 - Functional status (physical and psychosocial)
 - Patient's goal of therapy (level of pain acceptable and/or functional status)
 - 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** 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*)
 12. **For non-cancer pain:** Individual has been evaluated and must **not** have an active addiction to illicit substances or prescription drugs or a drug seeking behavior
 13. 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

BELBUCA™ (buprenorphine) buccal film (cont.)

14. **For non-cancer pain:** Belbuca is **NOT** being used in combination with any other long-acting opioid therapy
15. **For non-cancer pain:** Belbuca is **NOT** being used for the treatment of opioid dependence
16. There are **NO** contraindications.
 - Contraindications include:
 - Significant respiratory depression
 - Acute or severe bronchial asthma
 - Known or suspected gastrointestinal obstruction, including paralytic ileus
 - Hypersensitivity to buprenorphine or any components of the formulation

Initial approval duration:

- Belbuca will be approved at the requested dosage for 6 months for pain not related to cancer
- Belbuca 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*)

➤ **Criteria for continuation of coverage (renewal request):** Belbuca (buprenorphine) is considered **medically necessary** and will be approved when **ALL** of the following criteria are met:

1. Individual's pain is controlled
2. There is documentation that coordination of care is being performed between different prescribers for **ALL** controlled substances
3. The condition has not progressed or worsened while on therapy and no development of severe side effects like:
 - Apnea, dyspnea, epistaxis, hemoptysis, hyperventilation, hypoxia, upper respiratory infection etc.
 - Confusion/speech disturbance
 - Dehydration
 - Atrial fibrillation/arrhythmia/chest pain
 - Ascites
4. **For non-cancer pain:** A **treatment plan**, including:
 - Pain intensity (scales or ratings)
 - Functional status (physical and psychosocial)
 - Patient's goal of therapy (level of pain acceptable and/or functional status)
 - 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 **random urine or blood tests** twice a year



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7. **For non-cancer pain:** Documentation of **PDMP reviewed** 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*)
9. Belbuca is **NOT** being used in combination with any other long-acting opioid therapy
10. Belbuca is **NOT** being used for the treatment of opioid dependence
11. 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:

- Belbuca will be approved at the requested dosage for 12 months for pain not related to cancer
- Belbuca 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:

"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.

Description:

Belbuca (buprenorphine) buccal film is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. They should be reserved for use in patients for whom alternative treatment options (such as, non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. Belbuca (buprenorphine) buccal film is not indicated as an as-needed (prn) analgesic.

There are many other long-acting generically available opioid analgesics, including Morphine ER, Hydromorphone ER, Oxycodone ER, Oxymorphone ER, Methadone, and Fentanyl transdermal patches.

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 (Belbuca) compared to Schedule 2 Controlled Substances (Fentanyl,

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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.

Belbuca is a buccal dissolving film tablet that provides transmucosal delivery of buprenorphine.

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
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:

- 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

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- 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://pharmacympm.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/>
- 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](http://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		

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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. Package Insert. Revised by manufacturer 12/2016. Accessed 09-05-17.

Belbuca (buprenorphine) product information accessed 07-15-19 at DailyMed

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.



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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com. Call 866-325-1794 to check the status of a request. All requested data must be provided. Incomplete forms or forms without the chart notes will be returned. Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Opioid Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.

REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information			
Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:
Prescribing Provider Information			
Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	
Dispensing Pharmacy Information			
Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:	
Requested Medication Information			
Medication Name:	Strength:	Dosage Form:	
Directions for Use:	Quantity:	Refills:	Duration of Therapy/Use:
<input type="checkbox"/> Check if requesting brand only <input type="checkbox"/> Check if requesting generic			
<input type="checkbox"/> Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)			
Turn-Around Time For Review			
<input type="checkbox"/> Standard <input type="checkbox"/> Urgent. Sign here: _____ <input type="checkbox"/> Exigent (requires prescriber to include a written statement)			
Clinical Information			
1. Select all applicable diagnoses below. <input type="checkbox"/> Confirmed diagnosis of <u>pain severe</u> enough that is not controlled by the current dosage <input type="checkbox"/> Confirmed diagnosis of <u>Migraines</u> <input type="checkbox"/> Confirmed diagnosis of <u>Neuropathic Pain</u> <input type="checkbox"/> Confirmed diagnosis of <u>Osteoarthritis</u> <input type="checkbox"/> Confirmed diagnosis of <u>Fibromyalgia</u> <input type="checkbox"/> Other diagnosis: _____ ICD-10 Code(s): _____			
2. What is the quantity requested per day? _____			
3. What is the reason for <u>exceeding</u> the plan limitations? Please specify below (if applicable). _____			
4. For Migraines: Check all applicable <u>non-opioid</u> therapies failed, intolerated, or contraindicated. PREVENTATIVE TREATMENTS <input type="checkbox"/> Anticonvulsants (Topiramate) <input type="checkbox"/> Beta-Blockers (Propranolol, Atenolol) <input type="checkbox"/> TCAs (Amitriptyline, Imipramine) <input type="checkbox"/> Calcium Channel Blockers (Amlodipine, Verapamil) <input type="checkbox"/> Non pharmacological treatments (Cognitive behavioral therapy, Relaxation, Biofeedback, Exercise therapy) ACUTE TREATMENTS <input type="checkbox"/> Aspirin, Acetaminophen, NSAIDS (Naproxen, Ibuprofen, Meloxicam, Diclofenac) may be combined with caffeine <input type="checkbox"/> Anti-nausea medication (Ondansetron, Promethazine) <input type="checkbox"/> Triptans - migraine-specific (Rizatriptan, Sumatriptan)			
5. For Neuropathic Pain: Check all applicable <u>non-opioid</u> therapies failed, intolerated, or contraindicated. <input type="checkbox"/> TCAs (Amitriptyline, Imipramine) <input type="checkbox"/> SNRIs (Duloxetine, Venlafaxine) <input type="checkbox"/> Gabapentin/Lyrica <input type="checkbox"/> Topical Aspercreme 4% cream or Patches <input type="checkbox"/> Non pharmacological treatments (Exercise, Weight loss, patient education)			

Opioid Prior Authorization Request Form

6. For Osteoarthritis: Check all applicable non-opioid therapies failed, intolerated, or contraindicated.

FIRST LINE

- Acetaminophen
- Oral NSAIDs (Naproxen, Ibuprofen, Meloxicam, Diclofenac)
- Topical NSAIDs (Diclofenac Gel)

SECOND LINE

- Intra-articular hyaluronic acid (OA of the knee only)
- Capsaicin

7. For Fibromyalgia: Check all applicable non-opioid therapies failed, intolerated, or contraindicated.

- Duloxetine
- Lyrica
- Gabapentin
- TCAs (Amitriptyline, Imipramine)
- Non pharmacological treatments (Low impact aerobic exercise such as brisk walking, swimming, water aerobics or bicycling. Cognitive behavioral therapy, biofeedback, interdisciplinary rehabilitation)

8. Yes No A treatment plan must be submitted with this request form that includes ALL of the following:

- Pain intensity (scales or ratings)
- Functional status (physical and psychosocial)
- Patient's goal of therapy (level of pain acceptable and/or functional status)
- Current non-pharmacological treatment

9. Yes No A physician-patient pain management contract must be submitted with this request form.

10. Yes No Individual must not be actively using illicit substances or NOT have a drug seeking behavior.

11. Yes No Results from random urine or blood test twice a year must be submitted with this request form.

12. Yes No Has the state's Prescription Drug Monitoring Program (PDMP) been reviewed for this individual every time a prescription for controlled substance is provided?

13. What other controlled substances is the patient currently receiving? Please specify below.

14. One pharmacy (plus one closest 24 hour pharmacy) must be selected for all the controlled substances prescription services. Please specify:

15. Yes No There is NO concomitant use with benzodiazepines-ex. clonazepam, lorazepam, diazepam etc.

16. Yes No There is absence of ALL contraindications.

17. What medication(s) has the individual tried and failed for this diagnosis? Please specify below.

Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

18. Are there any supporting labs or test results? Please specify below.

Date	Test	Value

Opioid Prior Authorization Request Form

19. Is there any additional information the prescribing provider feels is important to this review? Please specify below.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature:

Date:

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.