

PHARMACY COVERAGE GUIDELINE

OPIOIDS LIMITATION FOR QUANTITY AND DOSAGE

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.**
- Information about medications that require prior authorization 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:

- An **exception** request on an opioid medication limitation for quantity, or dosage greater than **21 days** may be considered **medically necessary** and will be approved when **ALL** of the following criteria are met:
 1. Individual is 18 years of age or older
 2. Individual has a confirmed diagnosis of pain severe enough that is not controlled by the current quantity or dosage
 3. Individual has documented failure, contraindication per FDA label, intolerance, or is not a candidate for the following as clinically appropriate per diagnosis:
 - a. **MIGRAINES, both of the following categories:**
 - i. PREVENTATIVE TREATMENTS, a trial of one agent from each of the following:
 1. Anticonvulsant (e.g., topiramate)

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2. Beta-Blockers (e.g., propranolol, atenolol)
 3. TCAs (ex., amitriptyline, imipramine)
 4. Calcium Channel Blockers (ex., amlodipine, verapamil)
 5. A calcitonin gene-related peptide (CGRP) antagonist used for prevention (e.g., Ajovy, Emgality, Nurtec ODT, Qulipta, or Vyepti)
 6. Nonpharmacological treatments (e.g., Cognitive behavioral therapy, Relaxation, Biofeedback, Exercise therapy)
- ii. **ACUTE TREATMENTS**, a trial of one agent from each of the following:
1. Aspirin, acetaminophen, NSAIDS (e.g., naproxen, ibuprofen, meloxicam, diclofenac) may be combined with caffeine
 2. Anti-nausea medication (e.g., ondansetron, promethazine)
 3. Triptans - migraine-specific (e.g., rizatriptan, sumatriptan)
 4. A calcitonin gene-related peptide (CGRP) antagonist used for acute episodes (e.g., Nurtec ODT, Ubrelvy, or Zavzpret) or a serotonin 5HT1F receptor agonists (e.g., Reyvow)
- b. **NEUROPATHIC PAIN**, a trial of one agent from each of the following:
- i. TCAs (e.g., amitriptyline, imipramine)
 - ii. SNRIs (e.g., duloxetine, venlafaxine)
 - iii. Gabapentin/pregabalin (e.g., generic or brand Lyrica)
 - iv. Topical Aspercreme 4% cream or patches
 - v. Nonpharmacological treatments (e.g., Exercise, Weight loss, patient education)
- c. **OSTEOARTHRITIS**, a trial of one agent from each of the following:
- i. **FIRST LINE**
 1. Acetaminophen
 2. Oral NSAIDs (e.g., naproxen, ibuprofen, meloxicam, diclofenac)
 3. Topical NSAIDs (e.g., diclofenac gel)
 - ii. **SECOND LINE**
 1. Capsaicin
- d. **FIBROMYALGIA**, a trial of one agent from each of the following:
- i. Duloxetine
 - ii. Pregabalin (e.g., generic or brand Lyrica)
 - iii. Gabapentin
 - iv. TCAs (e.g., amitriptyline, imipramine)
 - v. Nonpharmacological treatments (e.g., Low impact aerobic exercise such as brisk walking, swimming, water aerobics or bicycling. Cognitive behavioral therapy, biofeedback, interdisciplinary rehabilitation)
- e. **OTHER CHRONIC PAIN INDICATION**, a trial of one agent from each of the following:
- i. Acetaminophen
 - ii. NSAIDs (e.g., naproxen, ibuprofen, meloxicam, diclofenac, etc.)
 - iii. Gabapentin
4. Individual has documentation of the treatment plan and diagnosis that provides the rationale for the exception on medication limitation for quantity or dosage

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5. There is documentation that coordination of care will be performed between different prescribers for **ALL** controlled substances
6. **For non-cancer pain:** For **morphine equivalent dosing (MED) greater than 180mg/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 less than 180mg/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 nonpharmacological treatment
8. **For non-cancer pain:** Physician-patient **pain management contract** must be provided
9. **For non-cancer pain:** Individual has been evaluated and must **not** have an active addiction to illicit substances or prescription drugs **OR** have 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 pharmacies, or multiple controlled substances)
10. **For non-cancer pain:** Documentation must be included for **random urine or blood tests** twice a year
11. **For non-cancer pain:** Documentation of **Prescription Drug Monitoring Program (PDMP) reviewed** by the prescriber every time a prescription for controlled substance is provided
12. **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*)
13. There is **NO** concomitant use with a benzodiazepine such as clonazepam, lorazepam, diazepam etc. **OR** there is a treatment plan to taper use and to coordinate care among all prescribers
14. There are **NO** FDA-label contraindications such as:
 - a. Significant respiratory depression
 - b. Acute or severe bronchial asthma
 - c. Known or suspected paralytic ileus or other GI obstruction
 - d. Moderate to severe hepatic impairment
 - e. Allergic reaction to opioid medication prescribed

Initial approval duration: 6 months

*For Affordable Care Act (ACA) Plans 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.

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- **Criteria for continuation of coverage (renewal request):** is considered *medically necessary* and will be approved when **ALL** the following criteria are met (**samples are not considered for continuation of therapy**):
- ONE** of the following:
 - Individual's pain is controlled with these products
 - Medication Assisted Treatment (MAT)
 - There is documentation that coordination of care is being performed between different prescribers for **ALL** controlled substances
 - Individual's condition has not progressed or worsened while on therapy and has not developed severe side effects such as:
 - Apnea, dyspnea, epistaxis, hemoptysis, hyperventilation, hypoxia, upper respiratory infection etc.
 - Confusion/speech disturbance
 - Dehydration
 - Atrial fibrillation/arrhythmia/chest pain
 - Ascites
 - 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
 - For non-cancer pain:** Physician-patient **pain management contract** must be provided
 - 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 pharmacies, or multiple controlled substances)
 - For non-cancer pain:** Documentation must be included for **random urine or blood tests** twice a year
 - For non-cancer pain:** Documentation of **Prescription Drug Monitoring Program (PDMP) reviewed** by the prescriber every time a prescription for controlled substance is provided
 - 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*)
 - There is **NO** concomitant use with a benzodiazepine such as clonazepam, lorazepam, diazepam etc. **OR** there is a treatment plan to taper use and to coordinate care among all prescribers

Renewal duration: 12 months

- 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:

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1. **Off-Label Use of Non-Cancer Medications**
 2. **Off-Label Use of Cancer Medications**
-

Description:

Medications are subject to limitations, including but not limited to, quantity, age, gender, and dosage. BCBSAZ determines which medications are subject to limitations based upon medication product labeling, nationally recognized compendia, or guidelines, and established clinical trials that have been published in peer reviewed professional medical journals. Medication limitations are subject to change at any time without prior notice. Providers may submit an exception request when medication limitations are exceeded or not met. However, a request is not a guarantee of coverage. Applicable benefit limitations and exclusions of the member's specific benefit plan may apply.

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
[MedWatch Forms for FDA Safety Reporting | FDA](#)

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:

A. Guidelines for Prescribing Opioids for Chronic Pain

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

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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

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

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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		

➤ **Warnings and Precautions:**

- a. Simultaneous use with another long-acting opioid drug
- b. Used on an as needed basis
- c. Used during immediate post-operative period
- d. Used for the treatment of mild pain
- e. Used for pain not expected to persist for an extended period of time
- f. Simultaneous use with opioid antagonist or opioid agonist-antagonist
- g. Simultaneous use with monoamine oxidase inhibitors (MAOIs) or within 14 days of stopping an MAOI
- h. Woman who is breast feeding an infant or child

Resources:

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.