BlueCross BlueShield Arizona

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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/or 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.

MEDICAL NECESSITY REQUIREMENTS FOR OPIOIDS LIMITATION FOR QUANTITY AND DOSAGE

Criteria for Initial Therapy:

Indication
- Confirmed diagnosis of pain severe enough that is not controlled by current quantity or dosage

Age Requirement
- 18 years or older

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Baseline Clinical Evaluation

- Documentation of treatment plan and diagnosis that provides rationale for exception on medication limitation for quantity or dosage
- Coordination of care documented between all prescribers of controlled substances
- **For non cancer pain:**
  - Treatment plan including:
    1. Pain intensity ratings
    2. Functional status
    3. Therapy goals
    4. Current non pharmacological treatments
  - Pain management contract between physician and patient
  - Evaluation confirming no active addiction or history of risky, harmful, or inappropriate substance use
  - Documentation of random urine or blood tests twice a year
  - Prescription Drug Monitoring Program (PDMP) reviewed by prescriber for each controlled substance prescription
  - Not used in combination with other long acting opioid therapy

Alternative Therapies

- Failure, contraindication per FDA label, intolerance, or is not a candidate for at least **ONE** pharmacologic non opiate therapy (e.g., acetaminophen, NSAIDs, gabapentin, pregabalin, TCA antidepressants, duloxetine, etc.)

Safety

- No concomitant use with benzodiazepines (e.g., clonazepam, lorazepam, diazepam, etc.) unless taper plan and coordinated care are documented
- No FDA labeled contraindications such as:
  - Significant respiratory depression
  - Acute or severe bronchial asthma
  - Known or suspected gastrointestinal obstruction including paralytic ileus
  - Moderate to severe hepatic impairment
  - Allergic reaction to opioid medication prescribed

Documentation Requirements

- A completed request form must be submitted including:
  - Chart notes
  - Lab results
  - Supporting clinical documentation

Initial Therapy Criteria Approval Duration

- 6 months OR end of plan year
- 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

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physician or other provider and to obtain all covered narcotic medications from one network pharmacy designated by BCBSAZ and/or the PBM.

Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy

Clinical Response

- Pain is controlled

Safety

- No concomitant use with benzodiazepines (e.g., clonazepam, lorazepam, diazepam, etc.) unless taper plan and coordinated care are documented
- No FDA labeled contraindications such as:
  - Significant respiratory depression
  - Acute or severe bronchial asthma
  - Known or suspected gastrointestinal obstruction including paralytic ileus
  - Moderate to severe hepatic impairment
  - Allergic reaction to opioid medication prescribed
- No severe side effects
  - Apnea, dyspnea, epistaxis, hemoptysis, hyperventilation, hypoxia, upper respiratory infection etc.
  - Confusion/speech disturbance
  - Dehydration
  - Atrial fibrillation/arrhythmia/chest pain
  - Ascites

Additional Requirements

- Coordination of care documented between all prescribers of controlled substances
- **For non cancer pain:**
  - Treatment plan including:
    1. Pain intensity ratings
    2. Functional status
    3. Therapy goals
    4. Current non pharmacological treatments
  - Pain management contract between physician and patient
  - Evaluation confirming no active addiction or history of risky, harmful, or inappropriate substance use
  - Documentation of random urine or blood tests twice a year
  - Prescription Drug Monitoring Program (PDMP) reviewed by prescriber for each controlled substance prescription

Documentation Requirements

- Chart notes
- Supporting clinical documentation with evidence of improvement in given indication
- Lab values confirming safe use

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Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

Criteria for Off-Label Use Requests:

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:

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

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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://pharmacypmp.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

Opioid Risk Assessment Tool:

Score each that applies	Female	Male
Family history of substance abuse		
Alcohol	1	3

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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		

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

Non-opiate treatment options:

A. **Migraine:**
- Preventative treatment
  - Anticonvulsant (e.g., topiramate)
  - Beta-blockers (e.g., propranolol, atenolol)
  - Tricyclic antidepressants (e.g., amitriptyline, imipramine)
  - Calcium channel blockers (e.g., amlodipine, verapamil)
  - Calcitonin gene-related peptide (CGRP) antagonist used for prevention (e.g., Ajovy, Emgality, Nurtec orally disintegrating tablet, Qulipta, Vyepti)
  - Botulinum toxin (e.g., Botox)
  - Nonpharmacological treatments (e.g., cognitive behavioral therapy, relaxation, biofeedback, exercise therapy)
- Acute treatment

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  - Aspirin, acetaminophen, nonsteroidal anti-inflammatory drugs (e.g., naproxen, ibuprofen, meloxicam, diclofenac) — may be combined with caffeine
  - Anti-nausea medication (e.g., ondansetron, promethazine)
  - Triptans — migraine-specific (e.g., rizatriptan, sumatriptan)
  - Calcitonin gene-related peptide (CGRP) antagonist used for acute episodes (e.g., Nurtec orally disintegrating tablet, Ubrelvy, Zavzpret)

B. **Neuropathic Pain**
- Tricyclic antidepressants (e.g., amitriptyline, imipramine)
- Serotonin-norepinephrine reuptake inhibitors (e.g., duloxetine, venlafaxine)
- Gabapentin or pregabalin (e.g., generic or brand Lyrica)
- Topical Aspercreme 4% cream or patches
- Nonpharmacological treatments (e.g., exercise, weight loss, patient education)

C. **Osteoarthritis,**
- First-line:
  - Acetaminophen
  - Oral nonsteroidal anti-inflammatory drugs (e.g., naproxen, ibuprofen, meloxicam, diclofenac)
  - Topical nonsteroidal anti-inflammatory drugs (e.g., diclofenac gel)
- Second-line: Capsaicin

D. **Fibromyalgia**
- Duloxetine
- Pregabalin (e.g., generic or brand Lyrica)
- Gabapentin
- Tricyclic antidepressants (e.g., amitriptyline, imipramine)
- Nonpharmacological treatments (e.g., low impact aerobic exercise such as brisk walking, swimming, water aerobics, bicycling; cognitive behavioral therapy; biofeedback; interdisciplinary rehabilitation)

Resources:

Dowell D, Ragan KR, Jones CM, et al. CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. *MMWR Recomm Rep* 2022;71(No. RR-3):1–95. DOI: http://dx.doi.org/10.15585/mmwr.rr7103a1

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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