

BENZODIAZEPINE LIMITATION FOR QUANTITY AND DOSAGE Generic Equivalent (if available)

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.

<u>Scope</u>

- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of outof-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 "<u>Criteria</u>" 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 "<u>Definition</u>" 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 <u>www.azblue.com/pharmacy</u>. You must fully complete the <u>request form</u> 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 <u>Pharmacyprecert@azblue.com</u>.

Criteria:

- An exception request for benzodiazepine medication limitation for quantity or dosage may be considered medically necessary and will be approved when ALL of the following criteria are met:
 - 1. Individual is between the age of 21 to 65 years of age (long term use of benzodiazepines is not recommended below 21 and above 65 years of age)
 - 2. Individual has failure, contraindication per FDA label, intolerance, or is not a candidate for at least 2 **benzodiazepine alternative therapies**:
 - a. Vistaril/Atarax 25-50mg TID
 - b. Propranolol 10-20mg TID caution low blood pressure
 - c. Buspirone 5-20mg TID
 - d. Pregabalin (generic or brand Lyrica) 50-150mg TID off label indication

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- e. Neurontin/Gabapentin 100-300mg TID off label indication
- f. SSRI or SNRI for anxiety disorder
- 3. Discontinue medications that increase anxiety i.e., stimulants, modafinil, bupropion, etc.
- 4. There is **NO** concomitant use with other benzodiazepines (i.e., temazepam, clonazepam, lorazepam, diazepam, etc.), **OR** benzodiazepine agonist (i.e., zolpidem, eszopiclone), <u>**OR**</u> opioids
- 5. Documentation of the treatment plan and diagnosis that provides the rationale for the exception on medication limitation for quantity or dosage
- 6. A treatment plan including:
 - a. Functional status (physical and psychosocial)
 - b. Patient's goal of therapy
 - c. Current nonpharmacological treatment
- 7. Coordination of care will be performed between different prescribers for ALL controlled substances
- Individual must NOT be actively using <u>illicit substances</u> 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)
- 9. Documentation must be included for random urine or blood tests twice a year
- 10. Documentation of <u>PDMP (Prescription Drug Monitoring Program) reviewed</u> by the prescriber every time a prescription for controlled substance is provided
- 11. Absence of ALL FDA-label contraindications such as:
 - a. Pregnancy and elderly
 - b. Renal, hepatic, and/or respiratory deficiency
 - c. Grief reactions
 - d. Active substance abuse—Drug testing is necessary before prescribing

Initial approval duration: 6 months

- Criteria for continuation of coverage (renewal request): An exception request for benzodiazepine medication limitation for quantity or dosage may be considered *medically necessary* and will be approved when ALL of the following criteria are met (samples are not considered for continuation of therapy):
 - 1. Continued coordination of care between different prescribers for ALL controlled substances
 - 2. The condition has not progressed or worsened while on therapy and has not developed severe side effects like:
 - a. Depression
 - b. Dysarthria
 - c. Emotional lability
 - d. Hallucination

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- e. Suicidal ideation
- f. There is 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)
- 3. Discontinue medications that increase anxiety i.e., stimulants, modafinil, bupropion etc.
- 4. There is **NO** concomitant use with other benzodiazepines (i.e., temazepam, clonazepam, lorazepam, diazepam, etc.), **OR** benzodiazepine agonist (i.e., zolpidem, eszopiclone), <u>**OR**</u> opioids
- 5. Documentation of the treatment plan and diagnosis that provides the rationale for the exception on medication limitation for quantity or dosage
- 6. A treatment plan including:
 - a. Functional status (physical and psychosocial)
 - b. Patient's goal of therapy
 - c. Current nonpharmacological treatment
- 7. Individual must **NOT** be actively using <u>illicit substances</u>
- 8. Documentation must be included for random urine or blood tests twice a year
- 9. Documentation of <u>PDMP (Prescription Drug Monitoring Program) reviewed</u> by the prescriber every time a prescription for controlled substance is provided
- 10. Absence of ALL FDA-label contraindications such as:
 - a. Pregnancy and elderly
 - b. Renal, hepatic, and/or respiratory deficiency
 - c. Grief reactions
 - d. Active substance abuse-Drug testing is necessary before prescribing

Renewal approval duration: 12 months

- Patients should be tapered off or lower the dosage if any of the following apply: See "Definitions" section for Tapering guidelines
 - There is 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)
 - The patient makes no progress toward therapeutic goals
- 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

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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

Indications for short-term use:

- Generalized anxiety disorder, phobias, PTSD, panic disorder, and severe anxiety associated with depression, while waiting for the full effect of the antidepressant.
- Insomnia—There is evidence for the effectiveness of benzodiazepines and other hypnotics in the relief of short-term (1 to 2 weeks), but not long-term insomnia.
- Muscle relaxant—Benzodiazepines are indicated for the short-term relief (1 to 2 weeks) of muscular discomfort associated with acute injuries or flare-ups of chronic musculoskeletal pain.
- Benzodiazepines may be combined with non-narcotic analgesics and nondrug therapies but not with other sedatives, hypnotics, or other muscle relaxants.
- Urgent treatment of acute psychosis with agitation
- As part of a protocol for treating alcohol withdrawal
- Seizures and a limited number of other neurological disorders
- Sedation for office procedures

Indications for long-term use:

- Benzodiazepines may be used for longer than 6 weeks in the terminally ill, in the severely handicapped patient, and in certain neurological disorders.
- Restless leg syndrome

Special considerations and contraindications:

- Pregnancy and elderly
- Renal, hepatic, and/or respiratory deficiency
- Grief reactions
- Active substance abuse—Drug testing is necessary before prescribing
- No evidence supports long-term use of benzodiazepines for a mental health disorder.

Tapering Benzodiazepines:

Basic principles:

Expect anxiety, insomnia, and resistance. Patient education and support very important.

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- The slower the taper, the better the better the change is tolerated.
- Only one provider should prescribe the benzodiazepine and should be agreed upon by the treatment team when patient is treated across specialties.
- Calculate exactly how many pills they will need and give only one prescription with no refills.
- Abrupt withdrawal is not recommended. Risk of seizures and/or delirium increases with abrupt withdrawal.

Slow Taper: (3-6 Months)

- 1. Calculate the total daily dose. Switch from short acting agent (alprazolam, lorazepam) to longer acting agent (diazepam, clonazepam). Upon initiation of taper, reduce the calculated dose by 25% to adjust for possible metabolic variance.
- 2. First Follow up is 1 week after initiating the taper to determine need to adjust initial calculated dose.
- 3. Reduce the total daily dose by 5-10% per week in divided doses.
- 4. Once ½ of the original dose has been reach, the taper can be slowed further by decreasing the dose each month thereafter.
- 5. Consider an adjunctive agent to help with symptoms or to replace the benzodiazepine such as: buspirone, Vistaril, clonidine, SSRIs, and/or sleeping aids.
- 6. Educate patient on nondrug therapies available to assist with symptoms such as: relaxation techniques, deep breathing, exercise, psychotherapy, etc.

Fast Taper: (2-6 Weeks)

- 1. Use an equivalent dose replace with Diazepam two times daily for 1-2 weeks.
- 2. Add an anticonvulsant (carbamazepine, valproate, gabapentin) at a maintenance dose. These work on the same GABA receptors and help to facilitate a faster taper.
- 3. Consider an adjunctive agent to help with symptoms or to replace the benzodiazepine such as: buspirone, Vistaril, clonidine, SSRIs, and/or sleeping aids. After 1-2 weeks decrease the dose of diazepam to once daily.
- 4. Then cut the diazepam to ¼ of the initial dose once daily for 1-2 weeks
- 5. Discontinue the Diazepam.
- 6. Continue the anticonvulsant for 2-3 months after discontinuing the benzodiazepine.
- 7. Educate patient on nondrug therapies available to assist with symptoms such as: relaxation techniques, deep breathing, exercise, psychotherapy, etc.

Approximate Equivalent Doses Benzodiazepines:	
Drug Name	Approximate Equivalent Dose
Alprazolam	0.5 mg
Chlordiazepoxide	25 mg
Clonazepam	0.5 mg
Diazepam	10 mg
Lorazepam	1 mg
Temazepam	20 mg

Benzodiazepine Alternatives:

Vistaril/Atarax 25-50mg TID Propranolol 10-20mg TID caution low blood pressure Buspirone 5-20mg TID Pregabalin (generic or brand Lyrica) 50-150mg TID off label indication Neurontin/Gabapentin 100-300mg TID off label indication

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SSRI or SNRI for anxiety disorder

Letter for New Prescriptions

Dear

You have been prescribed ______, one medication of a group of medicines known as the benzodiazepines. This medicine can help you cope with a short period of severe stress; it is not intended for long-term treatment and can be habit forming.

If you are being treated for sleeplessness or anxiety, you will be given tablets for a short period only. Longer treatment often makes sleep difficulties worse and may even make it difficult to stop the drug, so please understand why these will not be re-filled when they run out. Try to do without a tablet 1, 2 or 3 nights a week. Avoid alcoholic drinks when taking a benzodiazepine, particularly when first starting treatment. Do not drive or operate machinery while under the effects of these drugs.

Yours sincerely

Dr ___

Long Term Use Discontinuation Letter

Dear

I am writing to you because I note from our records that you have been taking ______ for some time now. Recently, doctors have become concerned about this kind of medication when it is taken over long periods. Our concern is that the

body can get used to these tablets so that they no longer work properly. If you stop taking the tablets suddenly, you may experience unpleasant withdrawal effects. For these reasons, repeated use of the tablets over a long time is no longer recommended. More importantly, these tablets may actually cause anxiety and sleeplessness and they can be addictive.

At our next appointment we will evaluate your current prescription and the short- and long-term goals of treatment with ______.

It is important to work with me in the tapering or discontinuation of this medicine. Please do not discontinue this medication until we have an opportunity to discuss a plan. Any change in the medication would involve a plan to prevent and or reduce

the likelihood of significant withdrawal symptoms.

We can discuss your prescription of ______ and alternative options that may be a good fit for your condition.

Yours sincerely,

Dr _____

Resources:

Westra HA, Stewart SH, Conrad BE. Naturalistic manner of benzodiazepine use and cognitive behavioral therapy outcome in panic disorder with agoraphobia. Journal of Anxiety Disorders 2002; 16 (3). Accessed April 14, 2023.

Vorma H et al. Long-term outcome after benzodiazepine withdrawal treatment in subjects with complicated dependence. Drug and Alcohol Dependence. 2003 June 5; 70(3). Accessed April 14, 2023.

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Morin CM et al. Long-term outcome after discontinuation of benzodiazepines for insomnia: A survival analysis of relapse. Behav Res Ther 2005 Jan; 43(1) 1-14. Accessed April 14, 2023

Clinical Guidelines for the Prescribing and Monitoring of Benzodiazepines and Related Medications. 2018 July 30. Available at: <u>https://dbhids.org/wp-content/uploads/2018/07/Clinical-Guidelines-for-Prescribing-and-Monitoring-Benzodiazepines.pdf</u>. Accessed April 14, 2023.

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