

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Benzodiazepines (Select Oral) Clinical Edit
<b>First Implementation Date:</b>	August 15, 2019
<b>Proposed Date:</b>	December 16, 2021
<b>Prepared for:</b>	MO HealthNet
<b>Prepared by:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input type="checkbox"/> Existing Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

## Executive Summary

**Purpose:** Ensure appropriate utilization and control of select oral benzodiazepines (alprazolam, chlordiazepoxide, clonazepam, clorazepate, diazepam, lorazepam, and oxazepam)

**Why Issue Selected:** Although all benzodiazepines possess anxiolytic properties, not all have FDA approval for treatment of generalized anxiety disorder which affects 3.1% of the U.S. population. The duration of benzodiazepine therapy for the acute management of anxiety should be limited to 2 to 4 weeks as they provide symptomatic relief but do not treat the underlying psychological problem. Participants with persistent symptoms should be managed with other therapies due to the risk of dependence with continued benzodiazepine therapy. Additionally, the American Geriatrics Society's 2019 Beers Criteria lists benzodiazepines as potentially inappropriate for use in patients aged 65 and older. In September 2020, the FDA updated the Boxed Warning for benzodiazepines to include the risks of abuse, misuse, addiction, physical dependence, and withdrawal reactions. The FDA has previously warned about the serious risks of combining benzodiazepines with opioid pain or cough medicines in August 2016, and about withholding medication for opioid use disorder from patients taking benzodiazepines or CNS depressants in September 2017.

With the implementation of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act, state Medicaid programs have new requirements regarding prescription drug utilization reviews. MO HealthNet is introducing new processes to monitor concurrent prescribing of opioids, benzodiazepines, and antipsychotics to meet the above requirements.

**Program-Specific Information:**

Date Range FFS 10-01-2020 to 9-30-2021			
Drug	Claims	Spend	Avg Spend per Claim
ALPRAZOLAM 0.25 MG TABLET	6,144	\$83,291.73	\$13.55
ALPRAZOLAM 0.5 MG TABLET	18,649	\$290,327.50	\$15.56
ALPRAZOLAM 1 MG TABLET	22,563	\$379,599.09	\$16.82
ALPRAZOLAM 2 MG TABLET	3,808	\$73,262.34	\$19.24
ALPRAZOLAM 0.25 MG ODT	37	\$2,600.13	\$70.27
ALPRAZOLAM 0.5 MG ODT	27	\$258.96	\$9.59
ALPRAZOLAM 1 MG ODT	4	\$146.25	\$36.56
ALPRAZOLAM 2 MG ODT	2	\$41.10	\$20.55

ALPRAZOLAM XR 0.5 MG TABLET	114	\$2,468.49	\$21.65
ALPRAZOLAM XR 1 MG TABLET	299	\$6,739.74	\$22.54
ALPRAZOLAM XR 2 MG TABLET	205	\$4,852.24	\$23.67
ALPRAZOLAM XR 3 MG TABLET	80	\$2,258.30	\$28.22
ALPRAZOLAM INTENSOL 1 MG/ML	0	-	-
CHLORDIAZEPOXIDE 5 MG CAPSULE	143	\$2,043.76	\$14.29
CHLORDIAZEPOXIDE 10 MG CAPSULE	236	\$3,252.91	\$13.78
CHLORDIAZEPOXIDE 25 MG CAPSULE	1,005	\$8,091.28	\$8.05
CLONAZEPAM 0.5 MG TABLET	29,313	\$451,881.76	\$15.41
CLONAZEPAM 1 MG TABLET	23,223	\$376,866.09	\$16.22
CLONAZEPAM 2 MG TABLET	2,925	\$43,360.62	\$14.82
CLONAZEPAM 0.125 MG ODT	548	\$17,517.39	\$31.96
CLONAZEPAM 0.25 MG ODT	1,020	\$34,571.66	\$33.89
CLONAZEPAM 0.5 MG ODT	757	\$31,745.49	\$41.93
CLONAZEPAM 1 MG ODT	693	\$29,619.43	\$42.74
CLONAZEPAM 2 MG ODT	375	\$10,209.34	\$27.22
CLORAZEPATE 3.75 MG TABLET	493	\$45,013.56	\$91.30
CLORAZEPATE 7.5 MG TABLET	411	\$53,023.34	\$129.01
CLORAZEPATE 15 MG TABLET	72	\$13,476.40	\$187.17
DIAZEPAM 2 MG TABLET	2676	\$33,532.10	\$12.53
DIAZEPAM 5 MG TABLET	11,131	\$141,102.88	\$12.67
DIAZEPAM 10 MG TABLET	6,972	\$111,473.08	\$15.98
DIAZEPAM 5 MG/5 ML SOLUTION	906	\$28,653.89	\$31.62
DIAZEPAM 5 MG/ML CONCENTRATE	31	\$1,931.76	\$62.31
LORAZEPAM 0.5 MG TABLET	13,478	\$192,243.76	\$14.26
LORAZEPAM 1 MG TABLET	14,928	\$198,242.47	\$13.28
LORAZEPAM 2 MG TABLET	2,457	\$39,721.95	\$16.16
LORAZEPAM INTENSOL 2 MG/ML	317	\$12,117.32	\$38.22
LOREEV XR 1 MG CAPSULE	0	-	-
LOREEV XR 2 MG CAPSULE	0	-	-
LOREEV XR 3 MG CAPSULE	0	-	-
OXAZEPAM 10 MG CAPSULE	14	\$1,028.11	\$73.43
OXAZEPAM 15 MG CAPSULE	29	\$1,540.39	\$53.11
OXAZEPAM 30 MG CAPSULE	14	\$1,263.26	\$90.23

Type of Criteria:  Increased risk of ADE  
 Appropriate Indications

Preferred Drug List  
 Clinical Edit

Data Sources:  Only Administrative Databases

Databases + Prescriber-Supplied

## Setting & Population

- Drug class for review: Select oral benzodiazepines (alprazolam, chlordiazepoxide, clonazepam, clorazepate, diazepam, lorazepam, and oxazepam)
- Age range: All appropriate MO HealthNet participants

## Approval Criteria

- Claim is within approved dosage limits for all indications **AND**
- Participants with diagnosis of a seizure disorder **or cerebral palsy** in the last 2 years requesting diazepam, clonazepam or clorazepate are not subject to:

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- Initial fill limitations **OR**
- Therapeutic trial of anxiolytic or SSRI/SNRI **OR**
- Claim is for a short-term indication (e.g., sedation for a procedure): MO HealthNet will approve up to a 3 day supply of a select oral benzodiazepine without prior authorization.
  - MO HealthNet will perform post pay audits to ensure the short supply is not being utilized inappropriately. Patterns of excessive claims for 3 day supply or less will be audited and may result in recoupment of claims **OR**
- Benzodiazepine naïve participants: Participants who have not received a select oral benzodiazepine in the past 90 days may receive up to a 15 day supply for an initial fill **OR**
- Benzodiazepine experienced participants (claim history of a select oral benzodiazepine in the past 90 days) - *It is MO HealthNet's intent to ensure participants utilize lower risk anxiolytic agents prior to initiation of long term, high risk benzodiazepine therapy by requiring therapeutic trials of other lower risk anxiolytic agents first.*
  - Participants with ≤ 30 days of therapy in the past year require an adequate trial of another anxiolytic (buspirone, doxepin or hydroxyzine trial defined as 60 days of therapy within the last year) **OR**
  - Participants with ≤ 60 days of therapy in the past 6 months may receive up to an additional 30 day supply of a select oral benzodiazepine **OR**
  - Participants with more than 60 days of therapy in the past 6 months must have one of the following:
    - An adequate trial of a SSRI or SNRI in the last 6 months **OR**
    - Demonstrated compliance to prescribed select oral benzodiazepine therapy
- For Klonopin Wafer:
  - Participant is less than 13 years of age **OR**
  - History of generic clonazepam oral tablets in the last year
- **For Loreev XR: Clinical Consultant Review required for medical necessity of long-acting agent**
- Participants not meeting the above criteria will undergo a Clinical Consultant Review upon provider request

## Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Participant is receiving > 1 benzodiazepine agent in the past 45 days (excluding any claims for ≤ 3 days supply)
- Participants receiving any combination of > 3 of the following drug classes in the past 30 days, **unless currently receiving Hospice or palliative care:**
  - Antipsychotics
  - Benzodiazepines
  - Opiate Dependence Agents
  - Opioids
  - Sedative Hypnotics
- Denial criteria contained within the High Risk Therapies Clinical Edit: Claim is for a select oral benzodiazepine and:
  - Participant has history of > 7 days of opioid therapy (excluding buprenorphine tablets and buprenorphine/naloxone combinations) in the past 60 days **AND**
  - Participant lacks history of at least 1 claim for an opioid emergency reversal agent in the past 2 years

## Required Documentation

Laboratory Results:   
 MedWatch Form:

Progress Notes:   
 Other:

## Disposition of Edit

Denial: Exception code "0682" (Clinical Edit)  
Rule Type: CE

## Default Approval Period

1 year

## Appendix A – Select oral benzodiazepines with max units per day (based upon usual and customary daily dosing)

Drug Description	Max Units Per Day
ALPRAZOLAM 0.25 MG TABLET	16
ALPRAZOLAM 0.5 MG TABLET	8
ALPRAZOLAM 1 MG TABLET	4
ALPRAZOLAM 2 MG TABLET	3
ALPRAZOLAM 0.25 MG ODT	16
ALPRAZOLAM 0.5 MG ODT	8
ALPRAZOLAM 1 MG ODT	4
ALPRAZOLAM 2 MG ODT	2
ALPRAZOLAM XR 0.5 MG TABLET	8
ALPRAZOLAM XR 1 MG TABLET	4
ALPRAZOLAM XR 2 MG TABLET	3
ALPRAZOLAM XR 3 MG TABLET	2
ALPRAZOLAM INTENSOL 1 MG/ML	4
CHLORDIAZEPOXIDE 5 MG CAPSULE	4
CHLORDIAZEPOXIDE 10 MG CAPSULE	4
CHLORDIAZEPOXIDE 25 MG CAPSULE	4
CLONAZEPAM 0.5 MG TABLET	4
CLONAZEPAM 1 MG TABLET	4
CLONAZEPAM 2 MG TABLET	2
CLONAZEPAM 0.125 MG ODT	4
CLONAZEPAM 0.25 MG ODT	4
CLONAZEPAM 0.5 MG ODT	4
CLONAZEPAM 1 MG ODT	4
CLONAZEPAM 2 MG ODT	2
CLORAZEPATE 3.75 MG TABLET	4
CLORAZEPATE 7.5 MG TABLET	4
CLORAZEPATE 15 MG TABLET	4
DIAZEPAM 2 MG TABLET	20
DIAZEPAM 5 MG TABLET	8
DIAZEPAM 10 MG TABLET	4
DIAZEPAM 5 MG/5 ML SOLUTION	40
DIAZEPAM 5 MG/ML CONCENTRATE	8
LORAZEPAM 0.5 MG TABLET	20
LORAZEPAM 1 MG TABLET	10
LORAZEPAM 2 MG TABLET	5
LORAZEPAM INTENSOL 2 MG/ML	5
<b>LOREEV XR 1 MG CAPSULE</b>	<b>2</b>
<b>LOREEV XR 3 MG CAPSULE</b>	<b>2</b>

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<b>LOREEV XR 2 MG CAPSULE</b>	<b>2</b>
OXAZEPAM 10 MG CAPSULE	12
OXAZEPAM 15 MG CAPSULE	8
OXAZEPAM 30 MG CAPSULE	4

## References

- Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act 2018. Available at: <https://www.congress.gov/bill/115th-congress/house-bill/6>
- Califf M, Ostroff S. "A Proactive Response to Prescription Opioid Abuse". The New England Journal of Medicine. 2016; 3741:1480-1485
- 2019 American Geriatrics Society Beers Criteria Update Expert Panel. American Geriatrics Society 2019 Updated AGS Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. Journal of the American Geriatrics Society. 2019
- Anxiety and Depression Association of America. Clinical practice review for GAD. Revised 2015. Available at: <https://adaa.org/resources-professionals/practice-guidelines-gad>
- Locke A, Kirst N, Schultz C. Diagnosis and management of generalized anxiety disorder and panic disorder in adults. American Family Physicians 2015; 91:617-624
- U.S. Food & Drug Administration. FDA requiring Boxed Warning updated to improve safe use of benzodiazepine drug class. <https://www.fda.gov/drugs/drug-safety-and-availability/fda-requiring-boxed-warning-updated-improve-safe-use-benzodiazepine-drug-class>. Updated September 30, 2020. Accessed November 8, 2021.

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