

SmartPA Criteria Proposal

Drug/Drug Class:	Benzodiazepines (Select Oral) Clinical Edit
First Implementation Date:	August 15, 2019
Proposed Date:	December 17, 2020
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	<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 10-01-2019 to 9-30-2020			
Drug	Claims	Spend	Avg Spend per Claim
ALPRAZOLAM 0.25 MG TABLET	7,189	\$121,388.99	\$16.89
ALPRAZOLAM 0.5 MG TABLET	21,436	\$400,273.66	\$18.67
ALPRAZOLAM 1 MG TABLET	26,440	\$527,250.25	\$19.95
ALPRAZOLAM 2 MG TABLET	4,742	\$108,089.62	\$22.78
ALPRAZOLAM 0.25 MG ODT	11	\$1,645.93	\$149.63
ALPRAZOLAM 0.5 MG ODT	20	\$732.13	\$41.69
ALPRAZOLAM 1 MG ODT	1	\$85.52	\$14.25
ALPRAZOLAM 2 MG ODT	1	\$220.67	\$36.77

ALPRAZOLAM XR 0.5 MG TABLET	108	\$2,455.55	\$22.78
ALPRAZOLAM XR 1 MG TABLET	314	\$8,221.62	\$26.18
ALPRAZOLAM XR 2 MG TABLET	188	\$5,306.60	\$28.24
ALPRAZOLAM XR 3 MG TABLET	83	\$2,630.45	\$31.80
ALPRAZOLAM INTENSOL 1 MG/ML	4	\$423.96	\$52.99
CHLORDIAZEPOXIDE 5 MG CAPSULE	156	\$2,976.55	\$19.36
CHLORDIAZEPOXIDE 10 MG CAPSULE	270	\$5,189.68	\$19.28
CHLORDIAZEPOXIDE 25 MG CAPSULE	1,161	\$10,078.56	\$8.72
CLONAZEPAM 0.5 MG TABLET	31,327	\$620,114.83	\$19.79
CLONAZEPAM 1 MG TABLET	25,805	\$536,140.41	\$20.78
CLONAZEPAM 2 MG TABLET	3,494	\$69,077.46	\$19.76
CLONAZEPAM 0.125 MG ODT	539	\$21,669.75	\$40.68
CLONAZEPAM 0.25 MG ODT	862	\$36,493.73	\$42.42
CLONAZEPAM 0.5 MG ODT	686	\$31,835.39	\$46.54
CLONAZEPAM 1 MG ODT	558	\$26,786.06	\$48.14
CLONAZEPAM 2 MG ODT	317	\$9,704.58	\$31.04
CLORAZEPATE 3.75 MG TABLET	507	\$56,186.01	\$111.00
CLORAZEPATE 7.5 MG TABLET	421	\$61,768.16	\$145.67
CLORAZEPATE 15 MG TABLET	99	\$17,969.46	\$181.21
DIAZEPAM 2 MG TABLET	2,707	\$45,690.77	\$16.89
DIAZEPAM 5 MG TABLET	12,749	\$209,931.53	\$16.48
DIAZEPAM 10 MG TABLET	7,568	\$151,229.51	\$19.98
DIAZEPAM 5 MG/5 ML SOLUTION	856	\$28,522.01	\$21.25
DIAZEPAM 5 MG/ML CONCENTRATE	44	\$2,138.21	\$48.24
LORAZEPAM 0.5 MG TABLET	14,811	\$259,973.1	\$17.54
LORAZEPAM 1 MG TABLET	16,243	\$270,630.59	\$16.66
LORAZEPAM 2 MG TABLET	2,586	\$50,888.43	\$19.67
LORAZEPAM INTENSOL 2 MG/ML	426	\$18,418.67	\$43.41
OXAZEPAM 10 MG CAPSULE	20	\$1,529.53	\$75.86
OXAZEPAM 15 MG CAPSULE	29	\$1,822.90	\$65.31
OXAZEPAM 30 MG CAPSULE	25	\$2,946.05	\$127.71

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**:
 - Claim is for ≤ 3 days supply for any indication at the provider's discretion **OR**
 - Participants with no history of benzodiazepine therapy within the past 90 days limited to 15-day supply with first fill **OR**
 - Participants who are benzodiazepine naïve (defined as ≤ 30 days of therapy in the last year): adequate therapeutic trial of buspirone, doxepin or hydroxyzine (defined as 60 days of therapy within the last year) **OR**

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- Participants with select oral benzodiazepine agent therapy length > 8 weeks:
 - Adequate trial of SSRI or SNRI in the last 6 months **OR**
 - Participant demonstrates compliance to prescribed therapy **OR**
 - Diagnosis of seizure disorder in the last 2 years: diazepam, clonazepam or **clorazepate** only
- For Klonopin Wafer:
 - Participant less than 13 years of age **OR**
 - History of generic clonazepam oral tablets in the last year
- Participants not meeting the above criteria will undergo a Clinical Consultant Review which may result in the need of a signed Benzodiazepine Attestation Form. Form will be provided by the Wipro Pharmacy Helpdesk if necessary.

Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Participants receiving > 1 benzodiazepine agents in the last 3 months (**excluding any claims for ≤ 3 days supply**)
- **Participants receiving any combination of > 3 of the following drug classes in the last 30 days:**
 - **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:

Progress Notes:

X
X

MedWatch Form:

Other:

Disposition of Edit

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

Default Approval Period

1 year

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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
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; 374:1480-1485

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- 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>. October 2, 2020.

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