



SmartPA Criteria Proposal

| | |
|-----------------------------------|--|
| Drug/Drug Class: | Benzodiazepines (Select Oral) Clinical Edit |
| First Implementation Date: | August 15, 2019 |
| Revised Date: | June 3, 2021 |
| 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 |

SmartPA Clinical Proposal Form

© 2021 Conduent Business Services, LLC. All rights reserved. Conduent™ and Conduent Design™ are trademarks of Conduent Business Services, LLC in the United States and/or other countries.

Other company trademarks are also acknowledged.

| | | | |
|--------------------------------|--------|--------------|----------|
| 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 Preferred Drug List
 Appropriate Indications 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**

SmartPA Clinical Proposal Form
© 2021 Conduent Business Services, LLC. All rights reserved. Conduent™ and Conduent Design™ are trademarks of Conduent Business Services, LLC in the United States and/or other countries.

Other company trademarks are also acknowledged.

- 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, **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 |
|------------------|-------------------|
|------------------|-------------------|

SmartPA Clinical Proposal Form
 © 2021 Conduent Business Services, LLC. All rights reserved. Conduent™ and Conduent Design™ are trademarks of Conduent Business Services, LLC in the United States and/or other countries.

Other company trademarks are also acknowledged.

| | |
|--------------------------------|----|
| 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; 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>

SmartPA Clinical Proposal Form

© 2021 Conduent Business Services, LLC. All rights reserved. Conduent™ and Conduent Design™ are trademarks of Conduent Business Services, LLC in the United States and/or other countries.

Other company trademarks are also acknowledged.

- 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.