SmartPA Criteria

Drug/Drug Class:	Benzodiazepines (Select Oral) Clinical Edit
First Implementation Date:	August 15, 2019
Revised Date:	October 10, 2019
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☒Revision of Existing Criteria ☐New Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of benzodiazepines.

Why was this Issue Selected: 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.

As a result of the FDA's Opioid Action Plan, drug labels for opioid analgesics, prescription opioid cough products and benzodiazepines now include a black box warning stating combined use can result in sedation, respiratory depression, coma and death. The agency's plan also includes associated risks when concurrently using opioids, benzodiazepines and skeletal muscle relaxants (also known as the "triple threat").

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.

Program-specific information:

Drug Class	Claims *(3/1/18-2/28/19)*	Spend *(3/1/18-2/28/19)*
Benzodiazepines (Select Oral)	*174,549*	*$3,918,638*

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

- Dosage within approved dosage limits for all indications AND below criteria
- Day supply ≤ 3 days for any indication at the providers discretion
- Participants with no history of benzodiazepine therapy within the past 90 days limited to 15-day supply with first fill
- If 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)
- If single selected 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
- If claim 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 no approval criteria are met
- Participant receiving > 1 benzodiazepine agents in the last 3 months (excluding any claims for ≤ 3 days supply)
- Participant receiving any combination of > 3 of the following drug classes in the last 30 days (will be monitored):
    - Antipsychotics
    - Benzodiazepines
    - Opiate Dependence Agents
    - Opioids
    - Sedative Hypnotics

Required Documentation

Laboratory results:	☐	Progress notes:	☐
MedWatch form:	☐	Other:	☐

Disposition of Edit

Denial: Exception Code “682” (Clinical Edit)

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

Drug Description	Generic Equivalent	Max Units Per Day
LIBRIUM 10 MG CAPSULE ORAL	CHLORDIAZEPOXIDE HCL	4
LIBRIUM 25 MG CAPSULE ORAL	CHLORDIAZEPOXIDE HCL	4
LIBRIUM 5 MG CAPSULE ORAL	CHLORDIAZEPOXIDE HCL	4
TRANXENE 15 MG TABLET ORAL	CLORAZEPATE DIPOTASSIUM	4
TRANXENE-T 3.75 MG TABLET ORAL	CLORAZEPATE DIPOTASSIUM	4
TRANXENE-T 7.5 MG TABLET ORAL	CLORAZEPATE DIPOTASSIUM	4
ATIVAN 0.5 MG TABLET ORAL	LORAZEPAM	20
ATIVAN 1 MG TABLET ORAL	LORAZEPAM	10
ATIVAN 2 MG TABLET ORAL	LORAZEPAM	5
VALIUM 10 MG TABLET ORAL	DIAZEPAM	4
VALIUM 2 MG TABLET ORAL	DIAZEPAM	20
VALIUM 5 MG TABLET ORAL	DIAZEPAM	8
OXAZEPAM 10 MG CAPSULE ORAL	OXAZEPAM	12
OXAZEPAM 15 MG CAPSULE ORAL	OXAZEPAM	8
OXAZEPAM 30 MG CAPSULE ORAL	OXAZEPAM	4
XANAX 0.25 MG TABLET ORAL	ALPRAZOLAM	16
XANAX 0.5 MG TABLET ORAL	ALPRAZOLAM	8
XANAX 1 MG TABLET ORAL	ALPRAZOLAM	4
XANAX 2 MG TABLET ORAL	ALPRAZOLAM	3
ALPRAZOLAM INTENSOL 1 MG/ML CONC	ALPRAZOLAM	4
XANAX XR 0.5 MG TAB ORAL	ALPRAZOLAM	8
XANAX XR 1 MG TAB ORAL	ALPRAZOLAM	4
XANAX XR 2 MG TAB ORAL	ALPRAZOLAM	3
KLONOPIN 0.5 MG TABLET ORAL	CLONAZEPAM	4
KLONOPIN 1 MG TABLET ORAL	CLONAZEPAM	4
KLONOPIN 2 MG TABLET ORAL	CLONAZEPAM	2
CLONAZEPAM 0.125 MG TAB RAPDIS ORAL	CLONAZEPAM	4
CLONAZEPAM 0.25 MG TAB RAPDIS ORAL	CLONAZEPAM	4
CLONAZEPAM 0.5 MG TAB RAPDIS ORAL	CLONAZEPAM	4
CLONAZEPAM 1 MG TAB RAPDIS ORAL	CLONAZEPAM	4
CLONAZEPAM 2 MG TAB RAPDIS ORAL	CLONAZEPAM	2
LORAZEPAM INTENSOL 2 MG/ML CONC	LORAZEPAM	5
XANAX XR 3 MG TAB ORAL	ALPRAZOLAM	2
ALPRAZOLAM 0.25 MG TAB RAPDIS ORAL	ALPRAZOLAM	16
ALPRAZOLAM 0.5 MG TAB RAPDIS ORAL	ALPRAZOLAM	8
ALPRAZOLAM 1 MG TAB RAPDIS ORAL	ALPRAZOLAM	4
ALPRAZOLAM 2 MG TAB RAPDIS ORAL	ALPRAZOLAM	2
DIAZEPAM 5 MG/5 ML SOLUTION ORAL	DIAZEPAM	40
DIAZEPAM 5 MG/ML ORAL CONC ORAL	DIAZEPAM	8
DIAZEPAM 5 MG/5 ML SOLUTION ORAL	DIAZEPAM	40

References:

1. 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

2. Califf M, Ostroff S. “A Proactive Response to Prescription Opioid Abuse”. *The New England Journal of Medicine.* 2016; 3741:1480-1485
3. U.S. Food and Drug Administration. FDA Opioids Action Plan. Available at: https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm484714.htm
4. 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
5. Anxiety and Depression Association of America. Clinical practice review for GAD. Revised 2015. Available at: https://adaa.org/resources-professionals/practice-guidelines-gad
6. 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