DRUG QUANTITY MANAGEMENT POLICY - PER RX

POLICY:

Benzodiazepine (selected) 14-Day Supply Dispensing Limit for InMynd – Drug Quantity Management Policy – Per Rx

- Ativan® (lorazepam tablets Bausch, generic)
- lorazepam oral concentrate generic only
- Klonopin[®] (clonazepam tablets Cheplapharm, generic)
- clonazepam orally disintegrating tablets (ODT) generic only
- Xanax[®] (alprazolam tablets Upjohn, generic)
- Xanax[®] XR (alprazolam extended-release tablets Upjohn, generic)
- alprazolam orally disintegrating tablets (ODT) generic only
- alprazolam intensol oral solution generic only
- Valium[®] (diazepam tablets Waylis, generic)
- diazepam oral solution generic only
- diazepam concentrate oral solution generic only

REVIEW DATE: 08/24/2022

OVERVIEW

Benzodiazepines, as a class, are indicated for use in a wide variety of conditions, including insomnia, anxiety disorders, seizure disorders, skeletal muscle relaxation, and alcohol withdrawal.¹⁻⁶ The benzodiazepines are differentiated by their pharmacokinetic profiles, which reflect differences in half-life (long-acting, intermediate-acting, and short-acting), onset of action (rapid, intermediate, or slow), and metabolic outcomes (with or without active metabolites).

Physiologic and psychological dependence occurs as a consequence of regular use of therapeutic doses. Because of these dependence consequences, this class of drugs is best avoided in patients with a history of substance abuse. Physiologic benzodiazepine dependence occurs as a consequence of regular use of benzodiazepines, but does not indicate drug misuse or abuse.

Benzodiazepines are best used in the short-term treatment of symptoms of acute anxiety, as temporary adjuncts to selective serotonin reuptake inhibitors (SSRIs) or serotonin and norepinephrine reuptake inhibitors (SNRIs) during treatment initiation, and for temporary use during periods of anxiety exacerbation during long-term treatment. Guidelines for the treatment of anxiety disorders, obsessive-compulsive disorder, and posttraumatic stress disorder recommend benzodiazepines as adjunctive therapy for a maximum of two to four weeks to reduce the risks of dependence and tolerance. Patients should be assessed regularly and the need for continued treatment should be evaluated.

Dosing

Dosing for the benzodiazepines varies depending on the therapeutic use.

Availability

The benzodiazepines within this policy include tablets, orally disintegrating tablets, oral solutions and oral concentrate solutions. As new products or dosage forms become available, they will roll into this policy and the list will be updated periodically.

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of benzodiazepines. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

<u>Automation</u>: This policy will target new users of the targeted benzodiazepine products only. If the patient has a history of one of the targeted benzodiazepines within the past 130 days, the claim will adjudicate. If the patient has a prescription for a cancer medication, anticonvulsant, antidepressant or antipsychotic (see appendices for STC codes/descriptions used) within a 180-day period, the claim will adjudicate. When available, ICD-10 codes for cancer/hospice, seizure disorders will be used as part of automation to allow approval of the requested medication (see appendices).

Drug Quantity Limits

A quantity sufficient for a 14-day supply will be covered without Prior Authorization. Additional quantities for greater than a 14-day supply will require coverage review.

CRITERIA

- **1.** Approve the quantity requested at retail or home delivery in patients who meet ONE of the following criteria (A, B, C, D, or E):
 - A) Patient has ONE of the following diagnoses (i, ii, iii, iv, or v):
 - **i.** Seizure disorder (e.g.; absence/petit-mal, atonic, tonic-clonic/grand mal, myoclonic, simple focal, complex focal, secondary generalized); OR
 - ii. Depression; OR
 - iii. Schizophrenia; OR
 - iv. Bipolar disorder; OR
 - v. Cancer; OR
 - **B)** Patient is in a hospice program, end-of-life care, or palliative care; OR
 - C) For patients who do not meet criteria A or B, approve if the patient meets the following criteria (i and ii):
 - i. According to the prescriber, the patient's history of controlled substance prescriptions has been checked using the state prescription drug monitoring program (PDMP); AND
 - **ii.** According to the prescriber, the risks (e.g., addiction, overdose) and realistic benefits of benzodiazepine therapy have been discussed with the patient.

REFERENCES

- 1. Reinhold JA and Rickels K. Pharmacological treatment for generalized anxiety disorder in adults: an update. *Expert Opin Pharmacother*. 2015;16(11):1669-1681.
- 2. Reinhold JA, Mandos LA, Rickels K and Lohoff FW. Pharmacological treatment of generalized anxiety disorder. *Expert Opin Pharmacother*. 2011;12(16);2457-2467.
- 3. Strawn JR, Geracioti L, Rajdev N, Clemenza K, and Levine A. Pharmacotherapy for generalized anxiety disorder in adult and pediatric patients: an evidence-based treatment review. *Expert Opin Pharmacother*. 2018;19(10)1057-1070.
- 4. Locke A, Kirst N, Shultz C. Diagnosis and Management of Generalized Anxiety Disorder and Panic Disorder in Adults. *Am Fam Physician*. 2015;91(9):617-624.
- 5. Katzman M, Bleau P, Blier P, et al. Canadian clinical practice guidelines for the management of anxiety, posttraumatic stress and obsessive-compulsive disorders. *BMC Psychiatry*. 2014;14(Suppl 1):S1.
- 6. Bandelow B, Michaelis S, Wedekind D. Treatment of anxiety disorders. Dialogues Clin Neurosci. 2017;19:93-106.

Type of Revision	Summary of Changes	Review Date
Annual Revision	No changes to criteria.	05/20/2021
Annual Revision	For patients who do not have a diagnosis of cancer, depression, bipolar disorder, schizophrenia, seizure disorder, or is not in hospice or end of life care: Criteria regarding checking the prescription drug monitoring program (PDMP) and criteria regarding discussion of the risks and benefits of treatment were modified to "according to the prescriber"; previously "prescribing physician". Criteria requiring that non-benzodiazepine therapies (e.g., selective serotonin receptor inhibitors [SSRI], serotonin and norepinephrine receptor inhibitors [SNRI], tricyclic antidepressant [TCA], or antipsychotics) have provided an inadequate response, or are inappropriate according to the prescriber, or benzodiazepines are needed as adjunctive treatment to existing therapies was removed. Removed "unless unavailable in the state" from criterion requiring the "patient's of controlled substance prescriptions has been checked using the state prescription drug monitoring program (PDMP)." Removed reference to Missouri not having a statewide PDMP (legislation was enacted in 2021).	08/24/2022
	Approval was clarified to state at retail or home delivery.	

APPENDICES

Note: These lists are not inclusive. As new drugs become available, they will roll into this policy and the list will be updated periodically.

Oncology Drugs

Oncology	21489
SK_STC	SK_STC_Desc
0473	ANTIBIOTIC ANTINEOPLASTICS
8585	ANTINEOPLAST HUM VEGF INHIBITOR RECOMB MC ANTIBODY
B759	ANTINEOPLAST, HISTONE DEACETYLASE (HDAC) INHIBITORS
0470	ANTINEOPLASTIC - ALKYLATING AGENTS
6323	ANTINEOPLASTIC - ANTIANDROGENIC AGENTS
H309	ANTINEOPLASTIC - ANTIBIOTIC AND ANTIMETABOLITE
G590	ANTINEOPLASTIC - ANTI-CD38 MONOCLONAL ANTIBODY
0471	ANTINEOPLASTIC - ANTIMETABOLITES
G607	ANTINEOPLASTIC - ANTI-SLAMF7 MONOCLONAL ANTIBODY
C593	ANTINEOPLASTIC - AROMATASE INHIBITORS
H617	ANTINEOPLASTIC - BRAF KINASE INHIBITORS
C370	ANTINEOPLASTIC - EPOTHILONES AND ANALOGS
D560	ANTINEOPLASTIC - HALICHONDRIN B ANALOGS
E150	ANTINEOPLASTIC - HEDGEHOG PATHWAY INHIBITOR
D426	ANTINEOPLASTIC - IMMUNOTHERAPY, THERAPEUTIC VAC
G545	ANTINEOPLASTIC - IMMUNOTHERAPY, VIRUS-BASED AGENTS
E039	ANTINEOPLASTIC - JANUS KINASE (JAK) INHIBITORS
G575	ANTINEOPLASTIC - MEK1 AND MEK2 KINASE INHIBITORS
C232	ANTINEOPLASTIC - MTOR KINASE INHIBITORS
I264	ANTINEOPLASTIC - PROTEIN METHYLTRANSFERASE INHIBIT
C532	ANTINEOPLASTIC - TOPOISOMERASE I INHIBITORS
E600	ANTINEOPLASTIC - VEGF-A,B AND PLGF INHIBITORS
F501	ANTINEOPLASTIC - VEGFR ANTAGONIST
0472	ANTINEOPLASTIC - VINCA ALKALOIDS
H317	ANTINEOPLASTIC- CD22 ANTIBODY-CYTOTOXIC ANTIBIOTIC

Oncology Drugs (continued)

SK_STC	SK_STC_Desc
H329	ANTINEOPLASTIC- CD33 ANTIBODY-CYTOTOXIC ANTIBIOTIC
H214	ANTINEOPLASTIC COMB - KINASE AND AROMATASE INHIBIT
8569	ANTINEOPLASTIC EGF RECEPTOR BLOCKER MCLON ANTIBODY
7977	ANTINEOPLASTIC IMMUNOMODULATOR AGENTS
8254	ANTINEOPLASTIC LHRH(GNRH) AGONIST,PITUITARY SUPPR.
8460	ANTINEOPLASTIC LHRH(GNRH) ANTAGONIST,PITUIT.SUPPRS
9150	ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS
H018	ANTINEOPLASTIC, PDGFR-ALPHA BLOCKER MC ANTIBODY
F665	ANTINEOPLASTIC,ANTI-PROGRAMMED DEATH-1 (PD-1) MAB
G802	ANTINEOPLASTIC-B CELL LYMPHOMA-2(BCL-2) INHIBITORS
H868	ANTINEOPLASTIC-CD123-DIRECTED CYTOTOXIN CONJUGATE
H324	ANTINEOPLASTIC-CD19 DIR. CAR-T CELL IMMUNOTHERAPY
H768	ANTINEOPLASTIC-CD22 DIRECT ANTIBODY/CYTOTOXIN CONJ
F495	ANTINEOPLASTIC-INTERLEUKIN-6(IL-6)INHIB,ANTIBODY
H289	ANTINEOPLASTIC-ISOCITRATE DEHYDROGENASE INHIBITORS
7235	ANTINEOPLASTICS ANTIBODY/ANTIBODY-DRUG COMPLEXES
0475	ANTINEOPLASTICS, MISCELLANEOUS
I054	ANTINEOPLASTIC-SELECT INHIB OF NUCLEAR EXP (SINE)
G857	ANTI-PROGRAMMED CELL DEATH-LIGAND 1 (PD-L1) MAB
D687	CYTOTOXIC T-LYMPHOCYTE ANTIGEN(CTLA-4)RMC ANTIBODY

^{*} Excluding topical products

Anticonvulsant Drugs

STC	STC Description
0275	ANTICONVULSANTS
H232	ANTICONVULSANTS - BENZO TYPE (except clonazepam)
H609	ANTICONVULSANTS - CANNABINOID TYPE

Antidepressants, Antipsychotic Drugs

Generic Name
AMITRIPTYLINE
AMOXAPINE
ARIPIPRAZOLE
ASENAPINE
BREXANOLONE
BREXPIPRAZOLE
BUPROPION
CARBAMAZEPINE
CARIPRAZINE
CHLORPROMAZINE HCL
CITALOPRAM
CLOMIPRAMINE
CLOZAPINE
DESIPRAMINE
DESVENLAFAXINE
DROPERIDOL
DOXEPIN
DULOXETINE
ESCITALOPRAM
ESKETAMINE
FLUPHENAZINE
FLUOXETINE
FLUVOXAMINE
HALOPERIDOL
ILOPERIDONE

Antidepressants, Antipsychotic Drugs (continued)

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Generic Name
IMIPRAMINE
ISOCARBOXAZID
LEVOMILNACIPRAN
LITHIUM
LOXAPINE
LUMATEPERONE
LURASIDONE
MAPROTILINE
MIRTAZAPINE
MOLINDONE
NEFAZODONE
NORTRIPTYLINE
OLANZAPINE
OLANZAPINE/FLUOXETINE

Antidepressants, Antipsychotic Drugs (continued)

Antidepressants, Antipsychotic Drugs
Generic Name
OLANZAPINE/SAMIDORPHAN MALATE
PALIPERIDONE
PAROXETINE
PERPHENAZINE
PERPHENAZINE/AMITRIPTYLINE
PHENELZINE
PIMAVANSERIN
PROTRIPTYLINE
QUETIAPINE
RISPERIDONE
SELEGILINE
SERTRALINE
THIORIZADINE
THIOTHIXENE
TRIFLUOPERAZINE HCL
TRANYLCYPROMINE
TRAZODONE
TRIMIPRAMINE
VENLAFAXINE
VILAZODONE
VORTIOXETINE
ZIPRASIDONE

ICD 10 CODES

*Indicates the inclusion of subheadings.