

DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

- POLICY:** Benzodiazepines – Diazepam (Oral) Drug Quantity Management Policy – Per Days
- Valium® (diazepam tablets – Roche Laboratories, generic)
 - diazepam oral solution – generic only
 - diazepam intensol™ oral solution (concentrate) – generic only

REVIEW DATE: 04/21/2022

OVERVIEW

The oral diazepam products are indicated:¹⁻³

- For the management of **anxiety disorders** or for the short-term relief of the symptoms of anxiety. Anxiety or tension associated with the stress of everyday life usually does not require treatment with an anxiolytic.
- In acute **alcohol withdrawal**, for the symptomatic relief of acute agitation, tremor, impending or acute delirium tremens and hallucinosis.
- As an adjunct for the relief of **skeletal muscle spasm** due to reflex spasm to local pathology (such as inflammation of the muscles or joints, or secondary to trauma), spasticity caused by upper motor neuron disorders (such as cerebral palsy and paraplegia), athetosis, and stiff-man syndrome.
- As an adjunct in **convulsive disorders**, although it has not proved useful as the sole therapy.

Dosing

The dose of diazepam is individualized for maximum benefit. Usual daily doses provided in Table 1 below will meet the needs of most patients; however, there will be some who may require higher doses.¹ In such cases dose should be increased cautiously to avoid adverse effects.

Table 1. FDA-Approved Dosing of Diazepam.¹

Adults	Dose
Management of anxiety disorders and relief of symptoms of anxiety	2 mg to 10 mg, BID to QID*
Symptomatic relief in acute alcohol withdrawal	10 mg, TID or QID during the first 24 hours, reduce to 5 mg, TID or QID as needed
Adjunctively for relief of skeletal muscle spasm	2 mg to 10 mg, TID or QID
Adjunctively in convulsive disorders	2 mg to 10 mg, BID to QID
Geriatric patients, or in the presence of debilitating disease	2 mg to 2.5 mg, QD or BID initially; increase gradually as needed and tolerated
Pediatric Patients	Dose
Because of varied responses to CNS-acting drugs, initiate therapy with lowest dose and increase as required. Not for use in pediatric patients < 6 months of age.	1 mg to 2.5 mg, TID or QID initially; increase gradually as needed and tolerated

BID – Twice daily; QID – Four times daily; * Depending on the severity of symptoms; TID – Three times daily; QD – Once daily; CNS – Central nervous system.

Availability

Diazepam is available as tablets (Valium, generic) in the following strengths: 2 mg, 5 mg, and 10 mg.¹ Diazepam is also available as an oral solution (5 mg/5 mL, in a 5 mL cup) as well as an oral concentrate solution (5 mg/mL, in a 30 mL bottle).^{2,3}

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of oral diazepam products. If the Drug Quantity Management rule is not met for the requested

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medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Automation: None.

Drug Quantity Limits

Product	Strength and Form	Maximum Quantity per 30 Days
Valium® (diazepam tablets, generic)	2 mg tablets	120 tablets*
	5 mg tablets	120 tablets*
	10 mg tablets	120 tablets*
Diazepam oral solution	5 mg/5 mL (5 mL cup)	1,200 mL
Diazepam intensol™ oral solution (concentrate)	5 mg/mL (30 mL bottle)	240 mL

* This quantity is sufficient to cover 30 days of therapy when dosed at the maximum frequency of four times a day.

CRITERIA

Valium 2 mg tablets (generic)

1. If the patient requires a dose greater than 8 mg per day, approve up to 600 tablets per 30 days.

Note: This quantity allows for a dose of up to 40 mg per day.

Valium 5 mg tablets (generic)

1. If the patient requires a dose greater than 20 mg per day, approve up to 240 tablets per 30 days.

Note: This quantity allows for a dose of up to 40 mg per day.

Valium 10 mg tablets (generics)

No overrides recommended.

diazepam 5 mg/5 mL oral solution

No overrides recommended.

diazepam intensol 5 mg/mL oral solution, concentrate

No overrides recommended.

REFERENCES

1. Valium® tablets [prescribing information] Little Falls, NJ: Roche Laboratories; February 2021.
2. diazepam intensol™ oral solution concentrate [prescribing information] Eatontown, NJ: West-Ward Pharmaceuticals; February 2021.
3. diazepam oral solution [prescribing information] Eatontown, NJ: West-Ward Pharmaceuticals; January 2021.