

QUANTITY LIMIT CRITERIA

DRUG CLASS	ANTI-ANXIETY AGENTS
BRAND NAME (generic)	ATIVAN (lorazepam)
	NIRAVAM (alprazolam orally disintegrating tablet)
	OXAZEPAM (oxazepam)
	TRANXENE (clorazepate)
	VALIUM (diazepam)
	XANAX (alprazolam)
Status: CVS Caremark Criteria	
Type: Quantity Limit	

POLICY

FDA-APPROVED INDICATIONS

Ativan

Ativan (lorazepam) is indicated for the management of anxiety disorders or for the short-term relief of the symptoms of anxiety or anxiety associated with depressive symptoms. Anxiety or tension associated with the stress of everyday life usually does not require treatment with an anxiolytic.

The effectiveness of Ativan (lorazepam) in long-term use, that is, more than 4 months, has not been assessed by systematic clinical studies. The physician should periodically reassess the usefulness of the drug for the individual patient.

Niravam

Generalized Anxiety Disorder

Niravam is indicated for the treatment of generalized anxiety disorder.

The efficacy of alprazolam in the treatment of generalized anxiety disorder was demonstrated in 5 short-term, placebo-controlled trials.

Panic Disorder

Niravam is also indicated for the treatment of panic disorder, with or without agoraphobia.

The efficacy of alprazolam in the treatment of panic disorder was established in 2 short-term, placebo-controlled trials.

Demonstrations of the effectiveness of Niravam by systematic clinical study are limited to 4 months in duration for generalized anxiety disorder and 4 to 10 weeks duration for panic disorder; however, patients

Anti-Anxiety Agents Limit Policy 05-2015

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with panic disorder have been treated on an open basis for up to 8 months without apparent loss of benefit. The physician should periodically reassess the usefulness of the drug for the individual patient.

Oxazepam

Oxazepam is indicated 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.

Anxiety associated with depression is also responsive to oxazepam therapy.

This product has been found particularly useful in the management of anxiety, tension, agitation and irritability in older patients.

Alcoholics with acute tremulousness, inebriation, or with anxiety associated with alcohol withdrawal are responsive to therapy.

The effectiveness of oxazepam in long-term use, that is, more than 4 months, has not been assessed by systematic clinical studies. The physician should periodically reassess the usefulness of the drug for the individual patient.

Tranxene

Tranxene is indicated 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.

Tranxene tablets are indicated as adjunctive therapy in the management of partial seizures.

The effectiveness of Tranxene tablets in long-term management of anxiety, that is, more than 4 months, has not been assessed by systematic clinical studies. Long-term studies in epileptic patients, however, have shown continued therapeutic activity. The physician should reassess periodically the usefulness of the drug for the individual patient.

Tranxene tablets are indicated for the symptomatic relief of acute alcohol withdrawal.

Valium

Valium (diazepam) is indicated 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, Valium (diazepam) may be useful in the symptomatic relief of acute agitation, tremor, impending or acute delirium tremens and hallucinosis.

Valium (diazepam) is a useful 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.

Oral Valium (diazepam) may be used adjunctively in convulsive disorders, although it has not proved useful as the sole therapy.

The effectiveness of Valium (diazepam) in long-term use, that is, more than 4 months, has not been assessed by systematic clinical studies. The physician should periodically reassess the usefulness of the drug for the individual patient.

Xanax

Anxiety Disorders

Xanax (alprazolam) is indicated for the management of anxiety disorder (a condition corresponding most closely to the APA Diagnostic and Statistical Manual [DSM-III-R] diagnosis of generalized anxiety disorder) or the short-term relief of symptoms of anxiety. Anxiety or tension associated with the stress of everyday life usually does not require treatment with an anxiolytic.

Generalized anxiety disorder is characterized by unrealistic or excessive anxiety and worry (apprehensive expectation) about two or more life circumstances, for a period of 6 months or longer, during which the person has been bothered more days than not by these concerns. At least 6 of the following 18 symptoms are often present in these patients: Motor Tension (trembling, twitching, or feeling shaky; muscle tension, aches, or soreness; restlessness; easy fatigability); Autonomic Hyperactivity (shortness of breath or smothering sensations; palpitations or accelerated heart rate; sweating, or cold clammy hands; dry mouth; dizziness or light-headedness; nausea, diarrhea, or other abdominal distress; flushes

or chills; frequent urination; trouble swallowing or 'lump in throat'); Vigilance and Scanning (feeling keyed up or on edge; exaggerated startle response; difficulty concentrating or 'mind going blank' because of anxiety; trouble falling or staying asleep; irritability). These symptoms must not be secondary to another psychiatric disorder or caused by some organic factor.

Anxiety associated with depression is responsive to Xanax (alprazolam).

Panic Disorder

Xanax (alprazolam) is also indicated for the treatment of panic disorder, with or without agoraphobia. Studies supporting this claim were conducted in patients whose diagnoses corresponded closely to the DSM-III-R/IV criteria for panic disorder.

Panic disorder (DSM-IV) is characterized by recurrent unexpected panic attacks, ie, a discrete period of intense fear or discomfort in which four (or more) of the following symptoms develop abruptly and reach a peak within 10 minutes: (1) palpitations, pounding heart, or accelerated heart rate; (2) sweating; (3) trembling or shaking; (4) sensations of shortness of breath or smothering; (5) feeling of choking; (6) chest pain or discomfort; (7) nausea or abdominal distress; (8) feeling dizzy, unsteady, lightheaded, or faint; (9) derealization (feelings of unreality) or depersonalization (being detached from oneself); (10) fear of losing control; (11) fear of dying; (12) paresthesias (numbness or tingling sensations); (13) chills or hot flushes. Demonstrations of the effectiveness of Xanax (alprazolam) by systematic clinical study are limited to 4 months duration for anxiety disorder and 4 to 10 weeks duration for panic disorder; however, patients with panic disorder have been treated on an open basis for up to 8 months without apparent loss of benefit. The physician should periodically reassess the usefulness of the drug for the individual patient.

REFERENCES

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10. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed May 2015.
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LIMIT CRITERIA

The intent is for the patient to receive only one drug from this drug class at a time; this quantity limit should accumulate across the entire anti-anxiety drug class.

	<u>1 Month Limit*</u>	<u>3 Month Limit*</u>
Ativan (0.5, 1, 2 mg) days	150 tablets/25 days	450 tablets/75
Lorazepam Intensol solution (2mg/mL)	150 mL/25 days	450 mL/75 days
Niravam (0.25, 0.5, 1 mg) days	90 tablets/25 days	270 tablets/75
Niravam (2mg) days	60 tablets/25 days	180 tablets/75
Oxazepam (10, 15, 30 mg) capsules/75 days	120 capsules/25 days	360
Tranxene (3.75, 7.5, 15 mg) days	120 tablets/25 days	360 tablets/75
Valium (2, 5, 10 mg) days	120 tablets/25 days	360 tablets/75
Diazepam solution (5mg/5mL) days	1200 mL/25 days	3600 mL/75
Diazepam Intensol solution (5mg/mL)	240 mL/25 days	720 mL/75 days
Xanax (0.25, 0.5, 1 mg) days	90 tablets/25 days	270 tablets/75
Xanax (2 mg) days	60 tablets/25 days	180 tablets/75
Alprazolam Intensol solution (1mg/mL)	120 mL/25 days	360 mL/75 days

**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*