# QUANTITY LIMIT CRITERIA

<table>
<thead>
<tr>
<th>DRUG CLASS</th>
<th>ANTI-ANXIETY AGENTS</th>
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</thead>
<tbody>
<tr>
<td>BRAND NAME (generic)</td>
<td>ATIVAN (lorazepam)</td>
</tr>
<tr>
<td></td>
<td>NIRAVAM (alprazolam orally disintegrating tablet)</td>
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<tr>
<td></td>
<td>OXAZEPAM (oxazepam)</td>
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<tr>
<td></td>
<td>TRANXENE (clorazepate)</td>
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<tr>
<td></td>
<td>VALIUM (diazepam)</td>
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<tr>
<td></td>
<td>XANAX (alprazolam)</td>
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</table>

**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...
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

2. Lorazepam Intensol oral solution (concentrate) [package insert]. Columbus, OH: Roxane Laboratories; October 2012.
**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.

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