

# Quantity Limit Criteria

## Anti-Anxiety Agents

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Alprazolam Intensol	alprazolam	oral solution concentrate
alprazolam (all brands)	alprazolam	orally disintegrating tablet
Ativan	lorazepam	all
chlordiazepoxide (all brands)	chlordiazepoxide	all
clonazepam (all brands)	clonazepam	orally disintegrating tablet
Diazepam Intensol	diazepam	oral solution concentrate
diazepam (all brands)	diazepam	oral solution
Klonopin	clonazepam	all
Lorazepam Intensol	lorazepam	oral concentrate solution
Loreev XR	lorazepam	extended-release
oxazepam (all brands)	oxazepam	all
Tranxene	clorazepate	all
Valium	diazepam	all
Xanax	alprazolam	all
Xanax XR	alprazolam extended-release	all

# Indications

## FDA-Approved Indications

### Alprazolam Orally Disintegrating Tablet

#### **Generalized Anxiety Disorder**

Alprazolam orally disintegrating tablets, USP are 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**

Alprazolam orally disintegrating tablets, USP are 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 alprazolam 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.

### Ativan, Lorazepam Intensol

Ativan (lorazepam) and lorazepam are 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) and 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.

### Chlordiazepoxide

Chlordiazepoxide HCl capsules are indicated for the management of anxiety disorders or for the short-term relief of symptoms of anxiety, withdrawal symptoms of acute alcoholism, and preoperative apprehension and anxiety. Anxiety or tension associated with the stress of everyday life usually does not require treatment with an anxiolytic.

The effectiveness of chlordiazepoxide HCl capsules 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.

## Klonopin, Clonazepam Orally Disintegrating Tablet

### Seizure Disorders

Klonopin and clonazepam orally disintegrating tablets are useful alone or as an adjunct in the treatment of the Lennox-Gastaut syndrome (petit mal variant), akinetic, and myoclonic seizures. In patients with absence seizures (petit mal) who have failed to respond to succinimides, Klonopin and clonazepam orally disintegrating tablets may be useful.

Some loss of effect may occur during the course of clonazepam treatment.

### Panic Disorder

Klonopin and clonazepam orally disintegrating tablets are indicated for the treatment of panic disorder, with or without agoraphobia, as defined in DSM-V. Panic disorder is characterized by the occurrence of unexpected panic attacks and associated concern about having additional attacks, worry about the implications or consequences of the attacks, and/or a significant change in behavior related to the attacks.

The efficacy of Klonopin and clonazepam orally disintegrating tablets was established in two 6- to 9-week trials in panic disorder patients whose diagnoses corresponded to the DSM-III-R category of panic disorder.

Panic disorder (DSM-V) is characterized by recurrent unexpected panic attacks, i.e., 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.

The effectiveness of Klonopin and clonazepam orally disintegrating tablets in long-term use, that is, for more than 9 weeks, has not been systematically studied in controlled clinical trials. The physician who elects to use Klonopin and clonazepam orally disintegrating tablets for extended periods should periodically reevaluate the long-term usefulness of the drug for the individual patient.

### Loreev XR

Loreev XR is indicated for the treatment of anxiety disorders in adults who are receiving stable, evenly divided, three times daily dosing with lorazepam tablets.

### Oxazepam

Oxazepam capsules are 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.

Reference number(s)
675-H

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, Diazepam Intensol, Diazepam Oral Solution

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

Valium and diazepam are 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 and oral diazepam may be used adjunctively in convulsive disorders, although it has not proved useful as the sole therapy.

The effectiveness of Valium and 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, Alprazolam Intensol

Xanax and Alprazolam are indicated for the:

- acute treatment of generalized anxiety disorder (GAD) in adults.

- treatment of panic disorder (PD), with or without agoraphobia in adults.

## Xanax XR

Xanax XR is indicated for the treatment of panic disorder with or without agoraphobia, in adults.

## Initial Limit Quantity

Limits should accumulate across all drugs and strengths up to the highest quantity listed depending on the order the claims are processed. Accumulation does not apply if limit is coded for daily dose.

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.

Drug	1 Month Limit	3 Month Limit
Alprazolam Intensol solution (1 mg / mL)	300 mL / 25 days	900 mL / 75 days
Alprazolam ODT (0.25 mg, 0.5 mg, 1 mg, 2 mg)	150 tablets / 25 days	450 tablets / 75 days
Ativan (0.5 mg, 1 mg, 2 mg)	150 tablets / 25 days	450 tablets / 75 days
Chlordiazepoxide (5 mg, 10 mg, 25 mg)	360 capsules / 25 days	1080 capsules / 75 days
Clonazepam ODT (0.125 mg, 0.25 mg, 0.5 mg, 1 mg, 2 mg)	300 tablets / 25 days	900 tablets / 75 days
Clorazepate (3.75 mg, 7.5 mg, 15 mg)	180 tablets / 25 days	540 tablets / 75 days
Diazepam solution (5 mg / 5 mL)	1200 mL / 25 days	3600 mL / 75 days
Diazepam Intensol solution (5 mg / mL)	240 mL / 25 days	720 mL / 75 days
Klonopin (0.5 mg, 1 mg, 2 mg)	300 tablets / 25 days	900 tablets / 75 days
Lorazepam Intensol solution (2 mg / mL)	150 mL / 25 days	450 mL / 75 days
Loreev XR (1 mg, 1.5 mg, 2 mg)	150 capsules / 25 days	450 capsules / 75 days
Loreev XR (3 mg)	90 capsules / 25 days	270 capsules / 75 days
Oxazepam (10 mg, 15 mg, 30 mg)	120 capsules / 25 days	360 capsules / 75 days
Tranxene (7.5 mg)	180 tablets / 25 days	540 tablets / 75 days
Valium (2 mg, 5 mg, 10 mg)	120 tablets / 25 days	360 tablets / 75 days

Reference number(s)
675-H

Drug	1 Month Limit	3 Month Limit
Xanax (0.25 mg, 0.5 mg, 1 mg, 2 mg)	150 tablets / 25 days	450 tablets / 75 days
Xanax XR (0.5 mg, 1 mg, 2 mg)	150 tablets / 25 days	450 tablets / 75 days
Xanax XR (3 mg)	90 tablets / 25 days	270 tablets / 75 days

## References

1. Alprazolam Intensol oral solution (concentrate) [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; January 2023.
2. Alprazolam Orally Disintegrating Tablet [package insert]. Chestnut Ridge, NY: Par Pharmaceutical, Inc.; April 2023.
3. Ativan [package insert]. Bridgewater, NJ: Bausch Health US, LLC; January 2023.
4. Chlordiazepoxide [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; December 2022.
5. Clonazepam Orally Disintegrating Tablet [package insert]. Chestnut Ridge, NY: Par Pharmaceutical; August 2022.
6. Diazepam Intensol oral solution (concentrate) [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; November 2022.
7. Diazepam oral solution [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; November 2022.
8. Klonopin [package insert]. Montgomery, AL: H2-Pharma, LLC; January 2023.
9. Lorazepam Intensol Oral Concentrate [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; January 2023.
10. Loreev XR [package insert]. Morristown, NJ: Almatica Pharma LLC; January 2023.
11. Oxazepam [package insert]. Parsippany, NJ: Teva Pharmaceuticals; August 2023.
12. Tranxene T-Tab [package insert]. Lebanon, NJ: Recordati Rare Diseases, Inc.; January 2023.
13. Valium [package insert]. Wixom, MI: Waylis Therapeutics LLC; October 2023.
14. Xanax [package insert]. New York, NY: Pharmacia and Upjohn Company LLC; January 2023.
15. Xanax XR [package insert]. New York, NY: Pharmacia and Upjohn Company LLC; January 2023.
16. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed January 08, 2024.
17. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed January 08, 2024.
18. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 01/08/2024).