

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS **TRICYCLIC ANTIDEPRESSANT (TCA) AGENTS – ELDERLY**

Quantity limits apply only to patients 65 years of age or older.

BRAND NAME

(generic)

(amitriptyline)

(amoxapine)

**ANAFRANIL
(clomipramine)**

(chlordiazepoxide/amitriptyline)

(doxepin)

(imipramine hydrochloride)

(imipramine pamoate)

**NORPRAMIN
(desipramine)**

**PAMELOR
(nortriptyline)**

(perphenazine/amitriptyline)

(protriptyline)

**SILENOR
(doxepin)**

(trimipramine)

Status: CVS Caremark® Criteria

Type: Post Limit Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

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Amitriptyline

Amitriptyline is indicated for the relief of symptoms of depression. Endogenous depression is more likely to be alleviated than are other depressive states.

Amoxapine

Amoxapine is indicated for the relief of symptoms of depression in patients with neurotic or reactive depressive disorders as well as endogenous and psychotic depressions. It is indicated for depression accompanied by anxiety or agitation.

Anafranil

Anafranil (clomipramine hydrochloride) capsules USP is indicated for the treatment of obsessions and compulsions in patients with Obsessive-Compulsive Disorder (OCD).

Chlordiazepoxide/Amitriptyline

Chlordiazepoxide and amitriptyline hydrochloride tablets are indicated for the treatment of patients with moderate to severe depression associated with moderate to severe anxiety.

The therapeutic response to chlordiazepoxide and amitriptyline hydrochloride tablets occurs earlier and with fewer treatment failures than when either amitriptyline or chlordiazepoxide is used alone.

Symptoms likely to respond in the first week of treatment include: insomnia, feelings of guilt or worthlessness, agitation, psychic and somatic anxiety, suicidal ideation and anorexia.

Doxepin

Doxepin HCl is recommended for the treatment of:

1. Psychoneurotic patients with depression and/or anxiety.
2. Depression and/or anxiety associated with alcoholism (not to be taken concomitantly with alcohol).
3. Depression and/or anxiety associated with organic disease (the possibility of drug interaction should be considered if the patient is receiving other drugs concomitantly).
4. Psychotic depressive disorders with associated anxiety including involutional depression and manic-depressive disorders.

The target symptoms of psychoneurosis that respond particularly well to doxepin include anxiety, tension, depression, somatic symptoms and concerns, sleep disturbances, guilt, lack of energy, fear, apprehension and worry.

Clinical experience has shown that doxepin is safe and well tolerated even in the elderly patient. Owing to lack of clinical experience in the pediatric population, doxepin is not recommended for use in children under 12 years of age.

Imipramine HydrochlorideDepression

For the relief of symptoms of depression. Endogenous depression is more likely to be alleviated than other depressive states. One to three weeks of treatment may be needed before optimal therapeutic effects are evident.

Childhood Enuresis

May be useful as temporary adjunctive therapy in reducing enuresis in children aged 6 years and older, after possible organic causes have been excluded by appropriate tests. In patients having daytime symptoms of frequency and urgency, examination should include voiding cystourethrography and cystoscopy, as necessary. The effectiveness of treatment may decrease with continued drug administration.

Imipramine Pamoate

For the relief of symptoms of depression. Endogenous depression is more likely to be alleviated than other depressive states. One to three weeks of treatment may be needed before optimal therapeutic effects are evident.

Norpramin

Norpramin is indicated for the treatment of depression.

Pamelor

Pamelor (nortriptyline HCl) is indicated for the relief of symptoms of depression. Endogenous depressions are more likely to be alleviated than are other depressive states.

Perphenazine/Amitriptyline

Perphenazine and amitriptyline hydrochloride tablets are recommended for treatment of (1) patients **with moderate to severe anxiety and/or agitation and depressed mood**, (2) patients with **depression in whom anxiety and/or agitation are severe**, and (3) patients **with depression and anxiety in association with chronic physical disease**. In many of these patients, anxiety masks the depressive state so that, although therapy with a tranquilizer appears to be indicated, the administration of a tranquilizer alone will not be adequate.

Schizophrenic patients who have associated depressive symptoms should be considered for therapy with perphenazine and amitriptyline hydrochloride tablets.

Protriptyline

Protriptyline hydrochloride tablets are indicated for the treatment of symptoms of mental depression in patients who are under close medical supervision. Its activating properties make it particularly suitable for withdrawn and anergic patients.

Silenor

Silenor is indicated for the treatment of insomnia characterized by difficulty with sleep maintenance. The clinical trials performed in support of efficacy were up to 3 months in duration.

Trimipramine

Trimipramine maleate capsules are indicated for the relief of symptoms of depression. Endogenous depression is more likely to be alleviated than other depressive states. In studies with neurotic outpatients, the drug appeared to be equivalent to amitriptyline in the less-depressed patients but somewhat less effective than amitriptyline in the more severely depressed patients. In hospitalized depressed patients, trimipramine and imipramine were equally effective in relieving depression.

COVERAGE CRITERIA

Agitation, Anxiety, Depression

Authorization may be granted for the requested drug when the ALL of the following criteria are met:

- The request is for ONE of the following:
 - Amitriptyline, amoxapine, desipramine, imipramine hydrochloride, imipramine pamoate, nortriptyline, protriptyline, or trimipramine for depression
 - Chlordiazepoxide/amitriptyline for depression associated with anxiety
 - Doxepin for depression and/or anxiety
 - Perphenazine/amitriptyline for depression with anxiety and/or agitation

QUANTITY LIMITS APPLY

POST LIMIT QUANTITY**			
Generic Drug (Brand if available)	Strength	1 Month Limit*	3 Month Limit*
amitriptyline	10 mg	180 tabs / 25 days	540 tabs / 75 days
amitriptyline	25 mg	120 tabs / 25 days	360 tabs / 75 days
amitriptyline	50 mg	90 tabs / 25 days	270 tabs / 75 days
amitriptyline	75 mg	60 tabs / 25 days	180 tabs / 75 days
amitriptyline	100 mg, 150 mg	30 tabs / 25 days	90 tabs / 75 days
amoxapine	25 mg, 50 mg, 100 mg	120 tabs / 25 days	360 tabs / 75 days
chlordiazepoxide/amitriptyline	5 mg/12.5 mg, 10 mg/25 mg	180 tabs / 25 days	540 tabs / 75 days
desipramine (Norpramin)	10 mg, 25 mg, 50 mg	120 tabs / 25 days	360 tabs / 75 days

desipramine (Norpramin)	75 mg, 100 mg	90 tabs / 25 days	270 tabs / 75 days
desipramine (Norpramin)	150 mg	60 tabs / 25 days	180 tabs / 75 days
doxepin	10 mg, 25 mg, 50 mg, 75 mg	120 caps / 25 days	360 caps / 75 days
doxepin	100 mg	90 caps / 25 days	270 caps / 75 days
doxepin	150 mg	60 caps / 25 days	180 caps / 75 days
doxepin	10 mg/mL	900 mL / 25 days	2,700 mL / 75 days
imipramine hydrochloride	10 mg, 25 mg	150 tabs / 25 days	450 tabs / 75 days
imipramine hydrochloride	50 mg	120 tabs / 25 days	360 tabs / 75 days
imipramine pamoate	75 mg, 100 mg	60 caps / 25 days	180 caps / 75 days
imipramine pamoate	125 mg, 150 mg	30 caps / 25 days	90 caps / 75 days
nortriptyline (Pamelor)	10 mg	180 caps / 25 days	540 caps / 75 days
nortriptyline (Pamelor)	25 mg, 50 mg	90 caps / 25 days	270 caps / 75 days
nortriptyline (Pamelor)	75 mg	60 caps / 25 days	180 caps / 75 days
nortriptyline	10 mg/5mL	2,250 mL / 25 days	6,750 mL / 75 days
perphenazine/amitriptyline	2 mg/10 mg	180 tabs / 25 days	540 tabs / 75 days
perphenazine/amitriptyline	2 mg/25 mg, 4 mg/25 mg	120 tabs / 25 days	360 tabs / 75 days
perphenazine/amitriptyline	4 mg/50 mg	90 tabs / 25 days	270 tabs / 75 days
protriptyline	5 mg	120 tabs / 25 days	360 tabs / 75 days
protriptyline	10 mg	180 tabs / 25 days	540 tabs / 75 days
trimipramine	25 mg, 50 mg	120 caps / 25 days	360 caps / 75 days
trimipramine	100 mg	60 caps / 25 days	180 caps / 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.*

***The initial limits for amoxapine 150 mg; clomipramine (Anafranil) 25 mg, 50 mg, 75 mg; doxepin (Silenor) 3 mg, 6 mg; and perphenazine/amitriptyline 4 mg/10 mg are set at the maximum adult daily doses. Additional quantities exceed the maximum adult daily dose; therefore, no post limit quantities will be available for these drugs.*

DURATION OF APPROVAL (DOA)

- 3406-J: DOA: 12 months

REFERENCES

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21. 2023 American Geriatrics Society Beers Criteria Update Expert Panel. American Geriatrics Society 2023 updated AGS Beers Criteria® for potentially inappropriate medication use in older adults. J Am Geriatr Soc. 2023; 71(7): 2052-2081. doi:10.1111/jgs.18372