

QUANTITY LIMIT CRITERIA

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|---------------------------------------|---|
| DRUG CLASS ELDERLY | TRICYCLIC ANTIDEPRESSANT (TCA) AGENTS – |
| BRAND NAME (generic) | (amitriptyline/perphenazine) |
| | (amoxapine) |
| | ANAFRANIL (clomipramine) |
| | (chlordiazepoxide/amitriptyline) |
| | (doxepin) |
| | ELAVIL (amitriptyline) |
| | (imipramine pamoate) |
| | LIMBITROL (chlordiazepoxide/amitriptyline) |
| | NORPRAMIN (desipramine) |
| | PAMELOR (nortriptyline) |
| | (protriptyline) |
| | SILENOR (doxepin) |
| | SURMONTIL (trimipramine) |
| | TOFRANIL |

TCA Agents (Elderly) Limit Policy 11-2017

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(imipramine hydrochloride)

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

Status: CVS Caremark Criteria

Type: Quantity Limit with Age Edit

POLICY

FDA-APPROVED INDICATIONS

Amitriptyline/Perphenazine

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.

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

Chlordiazepoxide/Amitriptyline

Chlordiazepoxide and amitriptyline hydrochloride is 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 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 hydrochloride capsules are recommended for the treatment of psychoneurotic patients with depression and/or anxiety, depression and/or anxiety associated with alcoholism (not to be taken concomitantly with alcohol), depression and/or anxiety associated with organic disease (the possibility of drug interaction should be considered if the patient is receiving other drugs concomitantly), psychotic depressive disorders with associated anxiety including involuntal depression and manic-depressive disorders.

Elavil

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

Imipramine Pamoate

Imipramine pamoate is indicated 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 (desipramine) 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.

Silenor

Silenor (doxepin) is indicated for the treatment of insomnia characterized by difficulty with sleep maintenance.

Surmontil

Surmontil (trimipramine) is indicated for the relief of symptoms of depression. Endogenous depression is more likely to be alleviated than other depressive states.

Tofranil

Tofranil (imipramine) is indicated for the relief of symptoms of depression. Endogenous depression is more likely to be alleviated than other depressive states. Tofranil is also indicated for childhood enuresis. It 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.

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.

REFERENCES

1. Amitriptyline [package insert]. Morgantown, WV: Mylan Pharmaceuticals; February 2017.
2. Amoxapine [package insert]. Parsippany, NJ: Actavis Pharma, Inc; February 2015.
3. Anafranil [package insert]. Hazelwood, MO: Mallinckrodt Inc; April 2017.
4. Doxepin [package insert]. Morgantown, WV: Mylan Pharmaceuticals; June 2015.
5. Elavil [package insert]. Birmingham, AL; Thompson Medical Solutions; April 2016.
6. Imipramine Pamoate [package insert]. Eatontown, NJ: West-Ward Pharmaceutical Corp; February 2017.
7. Norpramin [package insert]. Parsippany, NJ: Validus Pharmaceuticals LLC, January 2016.
8. Pamelor [package insert]. Hazelwood, MO: Mallinckrodt Inc; June 2014.
9. Silenor [package insert]. Morristown, NJ: Pernix Therapeutics LLC; October 2014.
10. Surmontil [package insert]. Horsham, PA: Teva Pharmaceuticals USA, Inc; February 2015.
11. Tofranil [package insert]. Hazelwood, MO: Mallinckrodt Inc; July 2014.
12. Protriptyline [package insert]. Eatontown, NJ: West-Ward Pharmaceuticals Corp.; April 2016.
13. Amitriptyline/Perphenazine [package insert]. Morgantown, WV: Mylan Pharmaceuticals; November 2016.
14. Chlordiazepoxide/Amitriptyline [package insert]. Morgantown, WV: Mylan Pharmaceuticals; D April 2017.
15. 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 November 2017.
16. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed November 2017.

LIMIT CRITERIA

Strengths not listed on this document have a quantity limit of 0 due to the dose of one unit per day would exceed the maximum elderly daily dose. These limits are only intended to address dosing for patients 65 years of age or older.

| | <u>1-Month Limit*</u> | <u>3-Month Limit*</u> |
|--|-----------------------|-----------------------|
| Amitriptyline 10 mg days | 150 units/25 days | 450 units/75 |
| Amitriptyline 25 mg days | 60 units/25 days | 180 units/75 |
| Amitriptyline 50 mg days | 30 units/25 days | 90 units/75 |
| Amitriptyline/Perphenazine 10 mg/2 mg days | 150 units/25 days | 450 units/75 |
| Amitriptyline/Perphenazine 10 mg/4 mg days | 120 units/25 days | 360 units/75 |
| Amitriptyline/Perphenazine 25 mg/2 mg, 25 mg/4 mg days | 60 units/25 days | 180 units/75 |
| Amitriptyline/Perphenazine 50 mg/4 mg days | 30 units/25 days | 90 units/75 |
| Amoxapine 25 mg, 50 mg, 100 mg days | 90 units/25 days | 270 units/75 |
| Amoxapine 150 mg days | 60 units/25 days | 180 units/75 |
| Anafranil 25 mg, 50 mg days | 150 units/25 days | 450 units/75 |
| Anafranil 75 mg days | 90 units/25 days | 270 units/75 |
| Chlordiazepoxide/Amitriptyline 10 mg/25 mg days | 60 units/25 days | 180 units/75 |
| Doxepin 10 mg, 25 mg, 50 mg days | 90 units/25 days | 270 units/75 |
| Doxepin 75 mg days | 60 units/25 days | 180 units/75 |
| Doxepin 100 mg, 150 mg days | 30 units/25 days | 90 units/75 |
| Doxepin 10 mg/mL days | 450 mL/25 days | 1,350 mL/75 |
| Imipramine pamoate 75 mg, 100 mg days | 30 units/25 days | 90 units/75 |

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|---------------------------------------|-------------------|--------------|
| Limbitrol 5 mg/12.5 mg days | 120 units/25 days | 360 units/75 |
| Norpramin 10 mg, 25 mg, 50 mg days | 90 units/25 days | 270 units/75 |
| Norpramin 75 mg days | 60 units/25 days | 180 units/75 |
| Norpramin 100 mg, 150 mg days | 30 units/25 days | 90 units/75 |
| Pamelor 10 mg days | 150 units/25 days | 450 units/75 |
| Pamelor 25 mg days | 60 units/25 days | 180 units/75 |
| Pamelor 50 mg days | 30 units/25 days | 90 units/75 |
| Pamelor 10 mg/5 mL days | 750 mL/25 days | 2,250 mL/75 |
| Silenor 3 mg, 6 mg days | 30 units/25 days | 90 units/75 |
| Surmontil 25 mg, 50mg days | 60 units/25 days | 180 units/75 |
| Surmontil 100 mg days | 30 units/25 days | 90 units/75 |
| Tofranil 10 mg, 25 mg days | 120 units/25 days | 360 units/75 |
| Tofranil 50 mg days | 60 units/25 days | 180 units/75 |
| Protriptyline 5 mg days | 90 units/25 days | 270 units/75 |
| Protriptyline 10 mg days | 60 units/25 days | 180 units/75 |

**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.*