Pharmacy Medical Necessity Guidelines: Antidepressant Medications

*Effective: April 1, 2019*

<table>
<thead>
<tr>
<th>Prior Authorization Required</th>
<th>√ Type of Review – Care Management</th>
<th>Not Covered</th>
<th>Type of Review – Clinical Review</th>
<th>√</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy (RX) or Medical (MED) Benefit</td>
<td>RX Department to Review</td>
<td>RXUM</td>
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</table>

These pharmacy medical necessity guidelines apply to the following:

**Commercial Products**
- Tufts Health Plan Commercial products – large group plans
- Tufts Health Plan Commercial products – small group and individual plans
- Tufts Health Freedom Plan products – large group plans
- Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

**Tufts Health Public Plans Products**
- Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
- Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
- Tufts Health RITogether – A Rhode Island Medicaid Plan

**Fax Numbers:**
RXUM: 617.673.0988

**Note:** This guideline does not apply to Medicare Members (includes dual eligible Members).

**OVERVIEW**

The table below highlights the FDA-approved indications for non-preferred antidepressants on the Tufts Health Together formulary.

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Major Depressive Disorder</th>
<th>Depression</th>
<th>Generalized Anxiety Disorder</th>
<th>Social Anxiety Disorder</th>
<th>Obsessive-Compulsive Disorder</th>
<th>Panic Disorder</th>
<th>Fibromyalgia</th>
<th>Diabetic Peripheral Neuropathic Pain</th>
<th>Diabetic Musculoskeletal Pain</th>
<th>Premenstrual Dysphoric Disorder</th>
<th>Vasomotor Symptoms</th>
<th>Depression w/ Bipolar 1</th>
<th>Treatment-resistant Depression</th>
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</thead>
<tbody>
<tr>
<td>Desvenlafaxine</td>
<td>Pristiq</td>
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<tr>
<td>Fluoxetine Tabs</td>
<td>Sarafem</td>
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<tr>
<td>Fluvoxamine extended-release</td>
<td>Luvox CR</td>
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<tr>
<td>Imipramine Pamoate</td>
<td>Tofranil-PM</td>
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<tr>
<td>Levomilnacipran</td>
<td>Fetzima</td>
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<td>Major Depressive Disorder</td>
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<td>Diabetic Peripheral Neuropathic Pain</td>
<td>Chronic Musculoskeletal Pain</td>
<td>Premenstrual Dysphoric Disorder</td>
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<tr>
<td>Paroxetine 7.5 mg</td>
<td>Brisdelle</td>
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<td>Protriptyline</td>
<td>Vivactil</td>
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<td>Selegiline Transdermal</td>
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<td>Trimipramine</td>
<td>Surmontil</td>
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<tr>
<td>Venlafaxine extended-release tablets</td>
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<td>Vilazodone</td>
<td>Viibryd</td>
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<td>Vortioxetine</td>
<td>Trintellix</td>
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<td>Olanzapine / fluoxetine</td>
<td>Symbyax</td>
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The goal of the MassHealth Pediatric Behavioral Health Medication Initiative (PBHMI) is to encourage safe prescribing of behavioral health medication regimens to members less than 18 years of age. As part of the PBHMI, a prior authorization is required for pediatric members less than 6 years of age who are being prescribed any antidepressant, regardless as to whether or not the antidepressant is preferred on the Plan’s formulary.

**COVERAGE GUIDELINES**

In addition to medication-specific prior authorization criteria list below, the Plan may authorize coverage of a preferred or non-preferred antidepressant medication for Members less than 6 years of age when the following criteria are met:

**Age-Specific Criteria for Members less than 6 years of age:**
1. Member has one of the following:
   a) Recent psychiatric hospitalization (within the last three months)
   **OR**
   b) History of severe risk of harm to self or others
   **OR**
2. All of the following criteria are met:
   a) An appropriate diagnosis
   **AND**
b) Treatment plan including the names of the Member’s current behavioral health medications and corresponding diagnoses

AND

c) The prescriber is a specialist (e.g., neurologist, psychiatrist) or a consult is provided

**Medication-specific criteria for all Members:**

1. Documentation the Member is stabilized on the requested medication for a duration of at least 2 months

OR

2. The Member recently started on the requested medication in an acute care setting, residential setting, or partial hospital setting

OR

3. One of the following medication-specific criteria:

**Desvenlafaxine**

1. The Member has tried and failed therapy with venlafaxine extended-release capsules or tablets

**Fluoxetine 10 mg, 20 mg tablets**

1. Documentation from the provider that treatment with fluoxetine 10 mg or 20 mg capsules is clinically inappropriate

**Fluoxetine tablets (Sarafem)**

1. Documentation the Member has tried and failed therapy with two alternative agents for premenstrual dysphoric disorder

**Fluvoxamine extended-release capsules**

1. Documentation the Member has tried and failed therapy, or has a contraindication to therapy, with immediate-release fluvoxamine and at least one alternative SSRI

**Levomilnacipran (Fetzima)**

1. Documentation the Member has tried and failed therapy with at least two alternative antidepressant agents, one of which must be an SNRI (e.g., venlafaxine, desvenlafaxine, duloxetine)

**Olanzapine/Fluoxetine (Symbyax)**

1. Documentation the Member has been stabilized on the individual agents, olanzapine and fluoxetine

**Paroxetine 7.5 mg capsules (Brisdelle)**

1. Documentation the Member has tried and failed therapy with two alternative agents for vasomotor symptoms of menopause

**Paroxetine extended-release tablets**

1. Documentation the Member has tried and failed therapy, or has a contraindication to therapy with immediate-release paroxetine and at least one other alternative SSRI

**Selegiline Transdermal (Emsam)**

1. Documented diagnosis of major depression

AND

2. Documentation the Member has been evaluated by a psychiatric prescriber

AND

3. One of the following:

a) Documentation the Member has had a favorable response to an oral MAOI AND is unable to continue treatment with an oral MAOI agent

OR
b) Documentation the Member has tried and failed treatment with at least one alternative agent from at least three alternative therapeutic classes (e.g., alpha-2 antagonists, norepinephrine dopamine receptor inhibitors, SSRIs, SNRIs, TCAs)

**Protriptyline or Trimipramine (Surmontil)**
1. Documentation the Member has tried and failed therapy with one alternative TCA

**Imipramine Pamoate**
1. Documentation the Member has tried and failed therapy with imipramine hydrochloride

**Venlafaxine ER Tablets**
1. Documentation the Member has tried and failed therapy with venlafaxine extended-release capsules

**Vilazodone (Viibryd)**
1. Documentation the Member has tried and failed therapy with at least two alternative SSRIs

**Vortioxetine (Trintellix)**
1. Documentation the Member has tried and failed therapy with two alternative antidepressants, one of which must be an SSRI

### LIMITATIONS

1. Requests for brand-name products, which have AB-rated generics, will be reviewed according to Non-covered Medications criteria.
2. The Plan will not approve continuation of therapy requests for non-preferred antidepressants if the same active ingredient in a different dosage form is preferred on the formulary. In that instance, the member must meet the specific approval criteria for the non-preferred dosage form.
3. Coverage is limited to the following:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trintellix (vortioxetine)</td>
<td>30 tablets per month</td>
</tr>
<tr>
<td>Duloxetine 20 mg and 60 mg</td>
<td>60 capsules per month</td>
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<tr>
<td>Duloxetine 30 mg</td>
<td>30 capsules per month</td>
</tr>
<tr>
<td>Emsam (selegiline)</td>
<td>30 patches per month</td>
</tr>
<tr>
<td>Fetzima (levomilnacipran)</td>
<td>30 tablets per month</td>
</tr>
<tr>
<td>Fluvoxamine extended-release</td>
<td>30 capsules per month</td>
</tr>
<tr>
<td>Paroxetine extended-release</td>
<td>30 tablets per month</td>
</tr>
<tr>
<td>Viibryd (vilazodone)</td>
<td>30 tablets per month</td>
</tr>
</tbody>
</table>

### CODES

None

### REFERENCES


9. Cymbalta ( duloxetine) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; December 2014.


14. Fetzima (levomilnacipran) [prescribing information]. Irvine, CA: Allergan USA, Inc; December 2017.


27. Sarafem (fluoxetine) [prescribing information]. Irvine, CA: Allergan USA, Inc; January 2017.


30. Sumontil (trimipramine) [prescribing information]. Horsham, PA: Teva Select Brands; 2014 July.


32. Tofranil-PM (imipramine pamoate) [prescribing information]. Whitby, Ontario, Canada: Patheon Inc.; June 2014.

33. Trintellix (vortioxetine) [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals; October 2018.

35. Vivactil (protriptyline) [prescribing information]. Horsham, PA: Teva Pharmaceuticals USA, Inc.; May 2014.

**APPROVAL HISTORY**
January 13, 2015: Reviewed by Pharmacy & Therapeutics Committee; Individual drug criteria consolidated into Antidepressant Agents Medical Necessity Guidelines.

Subsequent endorsement date(s) and changes made:
1. June 9, 2015: Incorporated criteria specific for Together Members less than 6 year of age; duration approval modified to two years.
2. August 11, 2015: Incorporated criteria for venlafaxine extended-release tablets and olanzapine/fluoxetine (Symbyax); approval duration modified to life of plan.
3. January 1, 2016: Administrative change to rebranded template.
4. March 8, 2016: Removed Limitation #3 “Quantities that exceed the quantity limit will be reviewed according to the Drugs w/ Quantity Limitations criteria.”
5. June 14, 2016: Prior authorization criteria added for fluoxetine 20 mg tablets. Updated Brintellix (vortioxetine) to new brand name Trintellix (vortioxetine).
6. August 9, 2016: Updated criteria for children less than 6 years of age.
7. September 13, 2016: Prior authorization criteria added for fluoxetine 10 mg tablets
8. November 15, 2016: Administrative update; clarified that members currently stable on a non-preferred dosage form must meet the approval criteria for that dosage form.
10. December 12, 2017: Administrative update, clarified the difference between age specific criteria for members less than 6 years of age and medication specific criteria for all members.
11. December 11, 2018: Effective 12/17/18, updated criteria for trimipramine to require only one trial of a TCA. Effective 4/1/19, updated criteria for imipramine pamoate to require trial and failure with imipramine hydrochloride. Administrative changes made to template.
12. Effective 4/1/2019, updated MNG to reflect that duloxetine (generic Cymbalta) is now covered on the Tufts Health Together formulary (note: PBHMI age and polypharmacy restrictions still apply).

**BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION**
Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member’s health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.