

Pharmacy Medical Necessity Guidelines: Antidepressant Medications

Effective: October 1, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
<p>These pharmacy medical necessity guidelines apply to the following:</p> <p>Commercial Products</p> <input type="checkbox"/> Tufts Health Plan Commercial products – large group plans <input type="checkbox"/> Tufts Health Plan Commercial products – small group and individual plans <input type="checkbox"/> Tufts Health Freedom Plan products – large group plans <input type="checkbox"/> Tufts Health Freedom Plan products – small group plans <ul style="list-style-type: none"> CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization <p>Tufts Health Public Plans Products</p> <input type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product) <input checked="" type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans <input type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan		<p>Fax Numbers: RXUM: 617.673.0988</p>	

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.

Generic Name	Brand Name	Major Depressive Disorder	Depression	Generalized Anxiety Disorder	Social Anxiety Disorder	Obsessive-Compulsive Disorder	Panic Disorder	Fibromyalgia	Diabetic Peripheral Neuropathic Pain	Chronic Musculoskeletal Pain	Premenstrual Dysphoric Disorder	Vasomotor Symptoms	Depression w/ Bipolar 1	Treatment-resistant Depression
Desvenlafaxine	Pristiq	X												
Duloxetine delayed-release	Drizalma	X		X					X	X				
Fluoxetine Tabs	Sarafem										X			
Fluvoxamine extended-release	Luvox CR					X								
Imipramine Pamoate	Tofranil-PM		X											
Levomilnacipran	Fetzima	X												

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Paroxetine 7.5 mg	Brisdelle											X		
Paroxetine extended-release	Paxil CR	X			X		X				X			
Protriptyline	Vivactil		X											
Selegiline Transdermal	Emsam Patch	X												
Trimipramine	Surmontil		X											
Venlafaxine extended-release tablets	Venlafaxine ER Tabs	X			X									
Vilazodone	Viibryd	X												
Vortioxetine	Trintellix	X												
Olanzapine / fluoxetine	Symbyax												X	X

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

Duloxetine delayed-release sprinkle capsules (Drizalma)

1. The Member has tried and failed generic duloxetine OR the provider submits documentation that the member has difficulty swallowing or has a nasogastric tube

AND

2. For the diagnosis of depression or anxiety,
a) Documentation the Member has tried and failed therapy with at least two different antidepressants from two different classes, such as a selective serotonin reuptake inhibitor (SSRI), a tricyclic antidepressant (TCA), a monoamine oxidase inhibitor (MAOI), or another serotonin-norepinephrine reuptake inhibitor (SNRI) (e.g., venlafaxine or desvenlafaxine)

OR

For the diagnosis of diabetic neuropathic pain,

- b) Documentation the Member has tried and failed therapy with at least two alternative agents for neuropathic pain, one being either gabapentin or pregabalin, and another being an antidepressant agent (e.g., a TCA, venlafaxine, desvenlafaxine) or another anticonvulsant agent (e.g., carbamazepine or lamotrigine)

OR

For the diagnosis of musculoskeletal pain,

- c) Documentation the Member has tried and failed therapy with at least three alternative therapies from at least two different therapeutic classes (e.g., analgesics, antidepressants, anticonvulsants, skeletal muscle relaxants)

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) and Vortioxetine (Trintellix)

1. Member has a documented diagnosis of major depressive disorder (MDD)

AND

2. Member is 18 years of age or older

AND

3. Documentation the Member has tried and failed therapy with two alternative antidepressants from two different therapeutic classes, 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. Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response or exception, but will be considered on an individual basis for prior authorization.
4. Coverage is limited to the following:

Trintellix (vortioxetine)	30 tablets per 30 days
Duloxetine 20 mg and 60 mg	60 capsules per 30 days
Duloxetine 30 mg	30 capsules per 30 days
Drizalma (duloxetine delayed-release sprinkle capsule) 20 mg, 60 mg	60 capsules per 30 days
Drizalma (duloxetine delayed-release sprinkle capsule) 30 mg, 40 mg	90 capsules per 30 days
Emsam (selegiline)	30 patches per 30 days
Fetzima (levomilnacipran)	30 tablets per 30 days
Fluvoxamine extended-release	30 capsules per 30 days
Paroxetine extended-release	30 tablets per 30 days

Viibryd (vilazodone)	30 tablets per 30 days
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CODES

None

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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.
9. May 9, 2017: Administrative update, Adding Tufts Health RITogether to the template.
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. March 12, 2019: 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).
13. November 12, 2019: Added criteria for Drizalma (duloxetine delayed-release sprinkle capsules).
14. July 14, 2020: Effective October 1, 2020, updated criteria for Trintellix and Viibryd. Added language concerning samples to limitations section of the MNG.

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.

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