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

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 RITogether 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 / fluoxotine	Symbyax												X	X

COVERAGE GUIDELINES

The Plan may authorize coverage of a non-preferred antidepressant medication when the following criteria are met:

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 providers 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 generic 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 generic 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 generic 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 generic 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

CODES

None

REFERENCES

1. American Psychiatric Association. Practice guideline for the treatment of patients with major depressive disorder, 3rd edition. 2010 November. URL: http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf. Available from Internet. Accessed 2016 February 19.
2. American Psychiatric Association (APA). Practice guideline for the treatment of patients with obsessive-compulsive disorder. 2007 July. URL: http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/ocd.pdf. Available from Internet. Accessed 2016 February 19.
3. American Psychiatric Association (APA). Guideline watch (2013): practice guideline for the treatment of patients with obsessive compulsive disorder. URL: https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/ocd-watch.pdf. Available from Internet. Accessed 2020 June 26.
4. American Psychiatric Association (APA). Practice guideline for the treatment of patients with panic disorder. 2009 January. URL: http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/panicdisorder.pdf. Available from Internet. Accessed 2016 February 19.
5. Anderson IM. Meta-analytical studies on new antidepressants. *Br Med Bull*. 2001;57:161-78.
6. Anderson IM. Selective serotonin reuptake inhibitors versus tricyclic antidepressants: a meta-analysis of efficacy and tolerability. *J Affect Disord*. 2000;58(1):19-36.

7. Asnis GM, Bose E, Gommoll CP, et al. Efficacy and safety of levomilnacipran sustained release 40 mg, 80 mg, or 120 mg in major depressive disorder: a phase 3, randomized, double-blind, placebo-controlled study. *J Clin Psychiatry*. 2013;74(3):242-8.
8. Bandelow B, Zohar J, Hollander E, et al. World Federation of Societies of Biological Psychiatry (WFSBP) guidelines for the pharmacological treatment of anxiety, obsessive–compulsive and post-traumatic stress disorders—first revisions. *World J Bioil Psychiatry.* 2008,9(4):248-312.
9. Brisdelle (paroxetine) [prescribing information]. Miami, FL: Noven Therapeutics, LLC; April 2017.
10. Cymbalta (duloxetine) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; December January.
11. Donohue JM, Pincus HA. Reducing the societal burden of depression: a review of economic costs, quality of care and effects of treatment. *Pharmacoeconomics.* 2007;25:7.
12. Dunn JD, Tierney JG. A step therapy algorithm for the treatment and management of chronic depression. *Am J Manag Care.* 2006 Oct;12(12 Suppl):S335-44.
13. Drizalma (duloxetine delayed-release) [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; July 2019.
14. Emsam (selegiline) [prescribing information]. Morgantown, WV: Somerset Pharmceuticals, Inc.; July 2017.
15. Fantino B, Moore N. The self-reported Montgomery-Asberg depression rating scale is a useful evaluative tool in major depressive disorder. *BMC Psychiatry*. 2009;9(26):1-6.
16. Fetzima (levomilnacipran) [prescribing information]. Madison, NJ: Allergan USA, Inc; October 2019.
17. Hansen RA, Gartlehner G, Lohr KN, et al. Efficacy and safety of second-generation antidepressants in the treatment of major depressive disorder. *Ann Intern Med*. 2005;143(6):415-26.
18. Iranikah M, Wensel TM, Thomason AR. Vilazodone for the treatment of major depressive disorder. *Pharmacotherapy*. 2012;32(10):958-65.
19. Kessler RC, Berglund P, Demler O, et al. The epidemiology of major depressive disorder: results from the National Comorbidity Survey Replication (NCS-R). *JAMA*. 2003;289(23):3095.
20. Luvox CR (fluvoxamine maleate) [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; January 2017.
21. Montgomery SA, Asberg M. A new depression scale designed to be sensitive to change. *Br J Psychiatry*. 1979;134:382-9.
22. National Institute for Health and Care Excellence. Depression in adults: recognition and management. 2009 October. URL: http://www.nice.org.uk/guidance/cg90. Available from Internet. Accessed 2016 February 19.
23. National Institute for Health and Care Excellence. Depression in children and young people: identification and management. 2015 March. URL: http://www.nice.org.uk/guidance/published?type=cg. Available from Internet. Accessed 2016 February 19.
24. Paxil CR (paroxetine) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline. September 2019.
25. Pristiq (desvenlafaxine) [prescribing information]. Philadelphia, PA: Wyeth Pharmaceuticals; March 2018.
26. Rickels K, Athanaisiou M, Robinson D, et al. Evidence for efficacy and tolerability of vilazodone in the treatment of major depressive disorder: a randomized, double-blind, placebo-controlled, trial. *Journal of Clinical Psychiatry.* 2009:70(3);326-33.
27. Sarafem (fluoxetine) [prescribing information]. Irvine, CA: Allergan USA, Inc; January 2017.
28. Sheehan DV, Harnett-Sheehan K, Raj BA. The measurement of disability. *Int Clin Psychopharmacol*. 1996;11(Suppl3):89-95.
29. Soleimani L, Lapidus KAB, Iosifescu DV. Diagnosis and treatment of major depressive disorder. *Neurol Clin*. 2011;29:177-93.
30. Surmontil (trimipramine) [prescribing information]. Horsham, PA: Teva Select Brands; July 2014.
31. Thomas KL, Ellingrod VL. Pharmacogenetics of selective serotonin reuptake inhibitors and associated adverse drug reactions. *Pharmacotherapy*. 2009;29(7):822-31.
32. Tofranil-PM (imipramine pamoate) [prescribing information]. Whitby, Ontario, Canada: Patheon Inc.; June 2014.
33. Trintellix (vortioxetine) [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals; July 2019.
34. Venlafaxine extended-release tablets [prescribing information]. Bridgewater, NJ: Vertical Pharmaceuticals, LLC; October 2016.
35. Vivactil (protriptyline) [prescribing information]. Horsham, PA: Teva Pharmaceuticals USA, Inc.; May 2014.
36. Viibryd (vilazodone) [prescribing information]. Madison, NJ: Allergan USA, Inc.; January 2020.

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, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether. Removed Pediatric Behavioral Health Medication (PBHMI) criteria.
10. December 12, 2017: No changes.
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 and updated criteria for brand products, specifying that previous trial requirements must be with generic agents. 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 RITogether formulary.
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.