

## Pharmacy Medical Necessity Guidelines: Antidepressant Medications

Effective: January 14, 2025

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: <input checked="" type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan		<b>Fax Numbers:</b> RXUM: 617.673.0939	

**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	Postpartum Depression
Bupropion/ dextromethorphan	Auvelity	X													
Desvenlafaxine	Pristiq	X													
Duloxetine delayed-release	Drizalma	X		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	
Zuranolone	Zurzuvae														X

### COVERAGE GUIDELINES

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

- Documentation the Member is stabilized on the requested medication for a duration of at least 2 months
- OR**
- The Member recently started on the requested medication in an acute care setting, residential setting, or partial hospital setting
- OR**
- One of the following medication-specific criteria:

#### Bupropion/dextromethorphan (Auvelity)

- The Member has had an inadequate response, adverse reaction, or contraindication to treatment with two antidepressants from two different classes, such as selective serotonin reuptake inhibitor (SSRI), a selective serotonin-norepinephrine inhibitor (SNRI), a tricyclic antidepressant (TCA), or a monoamine oxidase inhibitor (MAOI)

**Desvenlafaxine**

1. The Member has had an inadequate response, adverse reaction, or contraindication to treatment with venlafaxine extended-release capsules or tablets

**Duloxetine delayed-release sprinkle capsules (Drizalma)**

1. Documentation the member has a nasogastric tube or difficulty swallowing

**OR**

2. The Member meets **ALL** of the following:

- a) The Member has had an inadequate response, adverse reaction, or contraindication to generic duloxetine (Cymbalta)

**AND**

- b) The Member meets **ONE** of the following:

- i. The Member meets **ALL** of the following:

- A) The Member has a documented diagnosis of depression or anxiety

**AND**

- B) Documentation the Member has had an inadequate response, adverse reaction, or contraindication to treatment 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**

- ii. The Member meets **ALL** of the following:

- A) The Member has a documented diagnosis of diabetic neuropathic pain

**AND**

- B) Documentation the Member has had an inadequate response, adverse reaction, or contraindication to treatment with at least two alternative agents for neuropathic pain (e.g. gabapentin, pregabalin, a TCA, venlafaxine, desvenlafaxine, or another anticonvulsant [carbamazepine or lamotrigine])

**OR**

- iii. The Member meets **ALL** of the following:

- A) The Member has a documented diagnosis of musculoskeletal pain

**AND**

- B) Documentation the Member has had an inadequate response, adverse reaction, or contraindication to treatment with at least three alternative therapies from at least two different therapeutic classes (e.g., analgesics, antidepressants, anticonvulsants, skeletal muscle relaxants)

**OR**

- iv. The Member meets **ALL** of the following:

- A) The Member has a documented diagnosis of fibromyalgia

**AND**

- B) The Member has had an inadequate response, adverse reaction, or contraindication to treatment with at least two generic agents, such as gabapentin, pregabalin, or antidepressant medications (tricyclic antidepressants, selective serotonin reuptake inhibitors)

**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 had an inadequate response, adverse reaction, or contraindication to treatment with two generic alternative agents for premenstrual dysphoric disorder

**Fluvoxamine extended-release capsules**

1. Documentation the Member has had an inadequate response, adverse reaction, or contraindication to treatment with immediate-release fluvoxamine and at least one alternative SSRI

**Imipramine Pamoate**

1. Documentation the Member has had an inadequate response, adverse reaction, or contraindication to treatment with imipramine hydrochloride

**Levomilnacipran (Fetzima)**

1. Documentation the Member has had an inadequate response, adverse reaction, or contraindication to treatment 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 had an inadequate response, adverse reaction, and contraindication to treatment with two alternative agents for vasomotor symptoms of menopause

**Paroxetine extended-release tablets**

1. Documentation the Member has had an inadequate response, adverse reaction, or contraindication to treatment with immediate-release paroxetine and at least one other alternative SSRI

**Selegiline Transdermal (EMSAM)**

1. The Member meets **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 had an inadequate response, adverse reaction, or contraindication to treatment with at least one alternative generic agent from at least two alternative therapeutic classes (e.g., alpha-2 antagonists, norepinephrine dopamine receptor inhibitors, SSRIs, SNRIs, TCAs)

**Protriptyline and Trimipramine (Surmontil)**

1. Documentation the Member has had an inadequate response, adverse reaction, or contraindication to treatment with one alternative tricyclic antidepressant (TCA)

**Venlafaxine ER Tablets**

1. Documentation the Member has had an inadequate response, adverse reaction, or contraindication to treatment with venlafaxine extended-release capsules

**Vilazodone (Viibryd) and Vortioxetine (Trintellix)**

1. Documentation the Member has had an inadequate response, adverse reaction, or contraindication to treatment with two alternative generic antidepressants from two different therapeutic classes, one of which must be an SSRI

**Zuranolone (Zurzuvae)**

1. The Member was recently started on zuranolone in an acute care, residential, or partial hospital setting
- OR**
2. The Member meets **ALL** of the following:
    - a. Documented diagnosis of moderate to severe postpartum depression (PPD)

**AND**

    - b. Documentation the Member is postpartum for 12 months or less at the time of the request

**AND**

    - c. Onset of the depressive episode is between the third trimester and four weeks following delivery and has been documented by standardized rating scales such as the Beck Depression Inventory (BDI), Hamilton Depression Rating Scale (HDRS), Montgomery-Asberg Depression Rating Scale (MADRS), Quick Inventory and Depressive Symptomatology (QIDS, also known as QIDS-SR-16), or the Diagnostic and Statistical Manual of Mental Disorders (DSM 5) criteria

**AND**

- d. Documentation that the member has not responded adequately to a trial of an oral antidepressant, or clinical rationale that the trial of an oral antidepressant is not appropriate due to severity of depression (clinical documentation is required)

#### **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. For Zurzuvae (zuranolone), duration of approval is limited to one 14-day course per postpartum period. Approval will not be authorized if the member has previously received Zulresso (brexanolone) or Zurzuvae (zuranolone) for the current postpartum depressive episode from the most recent pregnancy.
5. Quantity limits are as follows:

<b>Drug Name</b>	<b>Quantity Limit</b>
Trintellix (vortioxetine)	1 tablet per day
Drizalma (duloxetine delayed-release sprinkle capsule) 20 mg, 60 mg	2 capsules per day
Drizalma (duloxetine delayed-release sprinkle capsule) 30 mg, 40 mg	3 capsules per day
EMSAM (selegiline)	1 patch per day
Fetzima (levomilnacipran)	1 tablet per day
Viibryd (vilazodone)	1 tablet per day/30 tablets per 30 days
Zurzuvae (zuranolone) 20 mg, 25 mg	2 capsules per day
Zurzuvae (zuranolone) 30 mg	1 capsule per day

#### **CODES**

None

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## APPROVAL HISTORY

September 13, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. November 8, 2022: Added criteria for Auvelity to the MNG. Updated Emsam criteria to reduce number of previous trials from three to two.
2. October 10, 2023: Effective January 1, 2024, updated the previous trial language to align with other MNGs. Updated Drizalma criteria to allow approval if the member has a nasogastric tube or difficulty swallowing and added criteria for the diagnosis of fibromyalgia. Updated Auvelity, Emsam, Trintellix, and Viibryd criteria to remove diagnosis requirement. Also updated Trintellix and Viibryd criteria to remove age requirement. Updated limitations section to remove statement that continuation of therapy requests for non-preferred antidepressants if the same active ingredient in a different dosage form is preferred on the formulary.
3. January 9, 2024: Effective February 1, 2024, added criteria for Zurzuvae to the MNG. Updated the fax number for RxUM.
4. January 14, 2025: No changes

## 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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