Pharmacy Medical Necessity Guidelines: Antidepressant Medications

Effective: July 1, 2017

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

This Pharmacy Medical Necessity Guideline applies to the following:

Tufts Health Plan Commercial Plans
✓ Tufts Health Plan Commercial Plans – large group plans
✓ Tufts Health Plan Commercial Plans – small group and individual plans

Tufts Health Public Plans
✓ Tufts Health Direct – Health Connector
□ Tufts Health Together – A MassHealth Plan
□ Tufts Health RITogether – A Rite Care + Rhody Health Partners Plan

Tufts Health Freedom Plan products
✓ Tufts Health Freedom Plan – large group plans
✓ Tufts Health Freedom Plan – small group plans

Fax Numbers:

RXUM: 617.673.0988

Note: For Tufts Health Plan Medicare Preferred Members, please refer to the Tufts Health Plan Medicare Preferred Step Therapy Criteria. Background, applicable product and disclaimer information can be found on the last page.

OVERVIEW

The plan has implemented a step therapy program for brand name antidepressants to encourage the first-line use of generic agents. The availability of several generic antidepressant agents has created an opportunity to improve the cost-effectiveness of treatment and lower prescription costs for patients without compromising efficacy.

Treating depression into remission is a key component of adequate care due to the negative impact of relapse and recurrence in depressive episodes. A logical and evidence-based method must be employed by managed care organizations in order to support and encourage adequate care. A step therapy algorithm provides one such manner by which treatment for depression can be delivered to efficiently improve patient outcomes and control escalating healthcare expenditures.

COVERAGE GUIDELINES

Note: Prescriptions that meet the initial step therapy requirements, will adjudicate automatically at the point of service. If the Member does not meet the initial step therapy criteria, the prescription will deny at the point of service with a message indicating that prior authorization (PA) is required. Refer to the Coverage Criteria below and submit PA requests to the plan using the Universal Pharmacy Medical Review Request Form for Members who do not meet the step therapy criteria at the point of service.

Members who are currently (within 180 days prior to the effective date) filling prescriptions for an antidepressant drug affected by this policy under the prescription benefit administered by the plan will be able to continue treatment on such existing drug regimen.

For Members who are new Members of the plan without prior claims history, physicians must provide documentation of prior use of a Step-2 or Step-3 antidepressant drug to continue treatment on such existing drug regimen.

Please refer to the table below for formularies and medications subject to this policy:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Tufts Health Plan Large Group Plans</th>
<th>Tufts Health Plan Small Group and Individual Plans</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step-1</td>
<td></td>
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<tr>
<td>budeprion SR</td>
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<tr>
<td>bupropion SR</td>
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</table>
Pharmacy Medical Necessity Guidelines: Antidepressant Medications

Tufts Health Plan Large Group Plans | Tufts Health Plan Small Group and Individual Plans
--- | ---
Bupropion XL | Covered
Citalopram HBr | Covered
Duloxetine | Covered
Escitalopram | Covered
Fluoxetine* | Covered
Fluoxetine delayed release | Covered
Fluvoxamine | Covered
Paroxetine HCl | Covered
Paroxetine ER | Covered
Sertaline | Covered
Venlafaxine | Covered
Venlafaxine ER | Covered

**Step-2**

Viibryd®
Desvenlafaxine ER
Desvenlafaxine Fumurate ER
Khedezla

**Step-3**

Aplenzin™
Emsam®
Forfivo XL™
Oleptro ER™
Pexeva™
Sarafem®
Trintellix

*Fluoxetine capsules are Step-1 and covered without restriction. Fluoxetine tablets are Step-1 but require prior authorization.

**Automated Step Therapy Coverage Criteria**
The following stepped approach applies to coverage of the Step-2 and Step-3 medications by the plan:

**Step 1**: Medications on Step-1 are covered without prior authorization.

**Step 2**: The plan may cover Step-2 medications if the following criteria are met:
- The Member is below 18 years of age.
- The Member has had a trial of a Step-1, Step-2 or Step-3 medication within the previous 180 days as evidenced by a previous paid claim under the prescription benefit administered by the plan.

**Step 3**: The plan may cover Step-3 medications if the following criteria are met:
- The Member has had a trial of a Step-2 or Step-3 medication within the previous 180 days as evidenced by a previous paid claim under the prescription benefit administered by the plan.

**Coverage Criteria for Members not meeting the Automated Step Therapy Coverage Criteria at the Point of Sale**
The following stepped approach applies to antidepressant medications covered by the plan:

**Step 2**: The plan may cover medications on Step-2 if the following criteria are met:
1. The Member is below 18 years of age OR
2. The Member has had a trial of a Step-1 or Step-2 medication as evidenced by physician’s documented use, excluding the use of samples OR
3. The Member has had a trial of a Step-3 medication as evidenced by physician-documented use, excluding the use of samples

**Note:** The plan may cover medications on Step-2 if a Member has received one of the **non-covered** medications, listed below under the limitations section, as evidenced by physician documented use, excluding the use of samples.

**Step 3:** The plan may cover medications on Step-3 if the following criteria are met:
1. The Member has had a trial of a Step-2 or Step-3 medication as evidenced by physician’s documented use, excluding the use of samples

**Note:** The plan may cover medications on Step-3 if a Member has received one of the **non-covered** medications, listed below under the limitations sections, as evidenced by physician documented use, excluding the use of samples.

**Additional Coverage Criteria for Duloxetine (Cymbalta)**
*Duloxetine (Cymbalta)* may be covered for Members when the following criteria are met and a prior authorization request to the plan using the Universal Pharmacy Medical Review Request Form is submitted:

**For Diabetic Peripheral Neuropathic Pain**
1. Physician documented diagnosis of neuropathic pain including pain associated with diabetic peripheral neuropathy AND
2. Documentation the Member has failed standard medication treatment and/or pain management, including gabapentin

**For Fibromyalgia**
1. Physician documented diagnosis of fibromyalgia AND
2. Documentation the Member has failed standard medication treatment and/or pain management, including gabapentin

**For Chronic Musculoskeletal Pain**
1. Physician documented diagnosis of chronic musculoskeletal pain including pain associated with osteoarthritis and chronic lower back pain AND
2. Documentation the Member has failed standard medication treatment and/or pain management, including two prescription analgesics

**Additional Coverage Criteria for Emsam (selegiline transdermal system)**
*Emsam* (selegiline transdermal system) may be covered for Members with major depressive disorder when the following criterion is met and a prior authorization request to the plan using the Universal Pharmacy Medical Review Request Form is submitted:
1. Physician documented inability to tolerate or contraindication to oral formulations of antidepressant medications in this step therapy

**Prior Authorization Criteria for Fluoxetine Tablets**
The plan may authorize coverage of fluoxetine tablets when **all** the following criteria are met:

1. Documentation from the provider that treatment with fluoxetine capsules is clinically inappropriate

**Note:** For daily doses of 60 mg, in addition to the above criterion, documentation of clinical inappropriateness of treatment with three 20 mg capsules is required for approval. For daily doses of 80 mg, in addition to the above criterion, documentation of clinical inappropriateness of treatment with two 40 mg capsules is required for approval.

**LIMITATIONS**
1. Medications on Step-2 or Step-3 are not covered unless the above step therapy criteria are met.
2. Previous use of samples or vouchers/coupons for brand name medications will not be considered for authorization.
3. The plan does not authorize coverage of **non-covered** antidepressant medications through this step therapy program. Non-covered antidepressant medications for all Commercial formularies include the following brand-name products: Celexa, Cymbalta, Effexor XR, Fetzima, Lexapro, Paxil, Paxil CR, Pristiq, Prozac, Prozac Weekly, Venlafaxine OSM 24 hr ER tablets, Wellbutrin, Wellbutrin SR, Wellbutrin XL and Zoloft. Please refer to the Pharmacy Medical Necessity Guidelines for Non-Covered Drugs with Suggested Alternatives and submit a formulary exception request to the plan as indicated.

4. The following antidepressant medications are not covered for the MA/RI EHB Formularies in addition to those noted above: Cymbalta and Lexapro. Please refer to the Pharmacy Medical Necessity Guidelines for Non-Covered Drugs with Suggested Alternatives and submit a formulary exception request to the plan as indicated.

5. Brand-name Wellbutrin products will not be authorized for smoking cessation.

6. Zyban® and its generic versions (Buproban, buproprion SR) are not part of the Antidepressant Medications Step Therapy Program. These products are indicated as aids to smoking cessation treatment and are covered with an annual limit of 90 days per calendar year (Massachusetts only). Please refer to the Pharmacy Medical Necessity Guidelines for Drugs with Quantity Limitations for additional details.

7. Coverage for Cymbalta ( duloxetine) will be limited as follows:

<table>
<thead>
<tr>
<th>DULOXETINE</th>
<th>COVERED AMOUNT</th>
</tr>
</thead>
<tbody>
<tr>
<td>20mg</td>
<td>60 capsules per 30 days 180 capsules per 90 days</td>
</tr>
<tr>
<td>30mg</td>
<td>90 capsules per 30 days 270 capsules per 90 days</td>
</tr>
<tr>
<td>60mg</td>
<td>60 capsules per 30 days 180 capsules per 90 days</td>
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</table>

**CODES**

None

**REFERENCES**


11. Cymbalta ( duloxetine) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; 2015 June.


19. Fetzima (levomilnacpran) [prescribing information]. St. Louis, MO: Forest Pharmaceuticals Inc; 2014 July.
23. Forfivo XL (bupropion) [prescribing information]. Austin, TX: Edgemont Pharmaceuticals, LLC, Inc.; 2014 June.
27. Lexapro (escitalopram) [prescribing information]. St. Louis, MO: Forest Pharmaceuticals, Inc.; 2014 October.
31. Oleptro (trazodone) [prescribing information]. Gaithersburg, MD: Angelini Labopharm; 2014 July.
36. Prozac (fluoxetine) [prescribing information]. Roorkee, India; Jubliant Generics Limited; 2015 August.
37. Prozac Weekly (fluoxetine) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; 2015 August.
43. Trintellix (vortioxetine) [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals; 2016 May.
45. Viibryd (vilazodone) [prescribing information]. St. Louis, MO: Forest Pharmaceuticals; 2015 March.
46. Wellbutrin (bupropion) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline, Inc.; 2014 December.
47. Wellbutrin SR (bupropion) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline, Inc.; 2014 December.

**APPROVAL HISTORY**

May 8, 2007: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- November 13, 2007: Added Antidepressant Medications Step Therapy program to Tufts Health Plan Medicare Preferred formulary.
- September 9, 2008: Added requirement of failure of standard medication treatment and/or pain management, including gabapentin for coverage of Cymbalta for the treatment of diabetic peripheral neuropathic pain.
- January 13, 2009: Added Venlafaxine OSM 24hr ER tablet to Step-2 of Antidepressant Medications Step Therapy program.
- July 14, 2009: Added Aplenzin to Step-3 of Antidepressant Medications Step Therapy program.
- November 10, 2009: Effective 1/1/2010, Wellbutrin XL 150mg is on Step-3 for the Tufts Health Plan Medicare Preferred formularies.
- January 1, 2010: Removal of Tufts Health Plan Medicare Preferred language (separate criteria have been created specifically for Tufts Health Plan Medicare Preferred).
- May 11, 2010: Added fluoxetine delayed release to Step-1 of Antidepressant Medications Step Therapy program.
- September 14, 2010: Added venlafaxine ER to Step-1 of Antidepressant Medications Step Therapy program. Added Oleptro ER to Step-3 of Antidepressant Medications Step Therapy program. Moved Effexor XR to Step-3 of Antidepressant Medications Step Therapy program.
- January 11, 2011: Added the newly approved indication of Chronic Musculoskeletal pain to the Cymbalta criteria.
- July 12, 2011: Removed the Non-covered list of drugs for Commercial. Removed Luvox from the Medical Necessity Guidelines as it has been discontinued by the manufacturer.
- September 9, 2011: Added historical look back period of 2 years for physician documented use of Step Therapy pre-requisite drugs.
- April 10, 2012: Moved Lexapro to Step-3 for Comm MA/RI and not covered for the GFF, added escitalopram to Step-1.
• June 12, 2012: Administrative update: removed historical look back period of 2 years for physician documented use of Step Therapy pre-requisite drugs.
• August 14, 2012: Removed Selfemra from Step-1, product has been discontinued. Added limitation that brand-name Lexapro, Olesent ER, Pexeva, Sarafem, and Venlafaxine OSM 24 hr ER tablet are not covered on the Generic Focused Formulary (GFF). Added note that non-covered products (Celexa, Effexor XR, Paxil, Paxil CR, Prozac, Prozac Weekly, Viibryd, Wellbutrin, Wellbutrin SR, Wellbutrin XL and Zoloft) may qualify as prerequisites for Step-2 or Step-3 medications. Added limitation that brand-name Wellbutrin products will not be authorized for smoking cessation. Added limitation regarding Zyban and its generics. These products are not part of this step therapy guideline. Added use of samples or vouchers/coupons for brand name medications limitation.
• November 6, 2012: Added Forfivo XL to Medical Necessity Guidelines.
• February 12, 2013: Added Viibryd to Step-2 of the Medical Necessity Guidelines for Comm MA/RI, still not covered for GFF.
• June 11, 2013: Added Desvenlafaxine ER to Step-2 of the Medical Necessity Guidelines for Comm MA/RI, not covered for the GFF.
• September 10, 2013: Effective 10/1/13; updated the quantity limit for Cymbalta 30 mg to 90 capsules per 30 days and the 60 mg to 60 capsules per 30 days.
• October 8, 2013: Administrative update: Removed requirement of 30-day trial and replaced with just a previous trial of the medication.
• January 14, 2014: Added Brintellix to the list of non-covered drugs. Added duloxetine to Step-1 and moved Cymbalta to Step-3 for COMM MA/RI and not covered for the GFF. Added Khedzela to Step-2 for Comm MA/RI and not covered for the GFF.
• March 11, 2014: Add Fetzima to the list of non-covered drugs.
• April 1, 2014: Administrative update: Removed language pertaining to the Generic Focused Formulary and added the EHB MA/RI Formulary.
• May 13, 2014: Added Desvenlafaxine Fumarate ER to Step-2 of the Medical Necessity Guidelines.
• March 10, 2015: For effective date April 1, 2015: Moved Cymbalta and Lexapro to not covered for the MA/RI EHB Formularies.
• January 1, 2016: Administrative change to rebranded template applicable to Tufts Health Direct.
• March 8, 2016: No changes.
• June 14, 2016: Updated Brintellix (vortioxetine) to new brand name Trintellix (vortioxetine).
• September 13, 2016: Added prior authorization criteria for fluoxetine tablets for an effective date of January 1, 2017. Moved Cymbalta, Lexapro, and Venlafaxine OSM 24 hr ER tablets to not covered for all Commercial formularies.
• April 11, 2017: Pristiq to not covered for the small group and individual and Tufts Health Direct formularies. Effective July 1, 2017 Move Pristiq to not covered for all LG COMM formularies and add Trintellix to Step-3. Administrative update, Adding Tufts Health RITogether to the template.

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. They are used in conjunction with a Member’s benefit document and in coordination with the Member’s physician(s). 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.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member's benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLinkSM Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.
For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

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.