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 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:

Drug	Tufts Health Plan Large Group Plans	Tufts Health Plan Small Group and Individual Plans
Step-1		
bupropion HCl	Covered	Covered
bupropion SR		
bupropion XL		
citalopram HBr		
duloxetine		

Drug	Tufts Health Plan Large Group Plans	Tufts Health Plan Small Group and Individual Plans
escitalopram	Covered	Covered
fluoxetine*		
fluvoxamine		
paroxetine HCl		
paroxetine ER		
sertraline		
venlafaxine		
venlafaxine ER		
Step-2		
Viibryd®	Requires prior use of a drug on Step-1, Step 2, or Step-3	Requires prior use of a drug on Step-1, Step 2, or Step-3
desvenlafaxine succinate ER		
desvenlafaxine fumerate ER		
Step-3		
Aplenzin™	Requires Prior Use of a Drug on Step-2 or Step-3	Requires Prior Use of a Drug on Step-2 or Step-3
Drizalma capsules		
Emsam®		
Pexeva™		
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 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 has had a trial of a Step-1, Step-2 or Step 3 medication as evidenced by physician's documented use

OR

2. The Member has a physician documented contraindication or intolerance to all Step-1 medications

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

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

OR

2. The Member has a physician documented contraindication or intolerance to all Step-1 and Step-2 medications

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

Additional Coverage Criteria for Pediatric Members 12 Years of Age and Younger
In addition to the step therapy criteria, all requests for a **non-preferred** antidepressant for members 12 years of age and younger must meet ALL of the following criteria

Preferred Agents for Pediatric Members 12 Years of Age and Younger	
fluoxetine	venlafaxine
fluvoxamine	citalopram
escitalopram	clomipramine
sertraline	imipramine
duloxetine	Fluoxetine-olanzapine (Symbyax)

1. Documentation that member has one of the following:
    a) recent psychiatric hospitalization (within the last three months)
    b) history of severe risk of harm to self or others

OR

2. Documentation that member is stable on the requested antidepressant for more than 2 months

OR

3. Documentation that the member has tried and failed at least 1 preferred agent (listed on the table above), as appropriate for the member's diagnosis

AND

4. The non-preferred antidepressant is prescribed by a specialist or in consultation with a specialist (psychiatrists, neurologist, etc.) or a developmental pediatrician

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:

1. Physician documented inability to tolerate or contraindication to oral formulations of antidepressant medications in this step therapy

Additional Coverage Criteria for Drizalma (duloxetine) delayed release sprinkle capsules
In addition to the step therapy criteria, **Drizalma (duloxetine)** delayed release sprinkle capsules may be covered for Members with major depressive disorder when the following criteria is met:

1. Documented evidence of dysphagia or difficulty swallowing, or the member has a nasogastric tube

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. Samples, free goods, or similar offerings of the requested medication do not quality for an established clinical response or exception but will be considered on an individual basis for prior 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, Duloxetine 40mg DR capsules, Effexor XR, Fetzima, fluoxetine weekly capsules, fluvoxamine ER capsules, Forfivo XL, Khedezla, Lexapro, Paxil, Paxil CR, Pristiq, Prozac, Prozac Weekly, Sarafem, Surmontil, 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. Brand-name Wellbutrin products will not be authorized for smoking cessation.

5. Zyban® and its generic versions (Buproban, bupropion 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.
6. Coverage for all formulations of duloxetine will be limited as follows:

Duloxetine 20mg	60 capsules per 30 days	180 capsules per 90 days
Duloxetine 30mg	90 capsules per 30 days	270 capsules per 90 days
Duloxetine 40mg	60 capsules per 30 days	180 capsules per 90 days
Duloxetine 60mg	60 capsules per 30 days	180 capsules per 90 days

CODES

None

REFERENCES

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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.
- July 8, 2008: Added restriction that the use of samples is excluded from evidence of a trial of a Step-2 or Step-3 Antidepressant Medication. Added Step-3 Antidepressant Medications as prerequisites for Step-2 drugs. Added Budeprion SR, Budeprion XL, paroxetine SR and Selfemra to Step-1 of Antidepressant Medications Step Therapy program. Added Pristiq to Step-2 of Antidepressant Medications Step Therapy program. Added Emsam to Step-3 of Antidepressant Medications Step Therapy program. Moved Paxil CR from Step-2 to Not Covered Status for the Tufts Health Plan Generic Focused Formulary. Moved Paxil CR from Step-2 to Step-3 for the Tufts Health Plan Commercial Formulary. Removed strength from bupropion XL to indicate that all strengths are covered on Step-1. Moved Wellbutrin XL 150 mg from Step-2 to Not Covered Status for the Tufts Health Plan Generic Focused Formulary. Moved Wellbutrin XL 150 mg from Step-2 to Step-3 for the Tufts Health Plan Commercial Formulary. Added criteria for coverage of Cymbalta for the treatment of fibromyalgia.
- 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.
- November 9, 2010: Effective January 1, 2011: Moved Celexa, Effexor XR, Paxil, Paxil CR, Prozac, Prozac Weekly, Rapiflux, Wellbutrin, Wellbutrin SR, Wellbutrin XL, and Zoloft to not covered for Commercial MA/RI. Removed Effexor from Step Therapy due to discontinuation of the brand. Moved Venlafaxine OSM ER to Step-3 of the Antidepressant Medications Step Therapy Program for Commercial MA/RI and not covered for GFF.
- 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, Oleptro ER, Pexeva, Sarafem and Venlafaxine OSM 24hr 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 Fumurate 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.
- February 13, 2018: Reflected the change in coverage of Sarafem- Removed from Step-3 and added to NC list. Sarafem moved to NC for the small groups and individual and Tufts Health Direct formularies. Effective April 1, 2018, Sarafem will move to NC for all LG COMM formularies.
- August 7, 2018: Administrative update: removed budeprion SR, budeprion XL and Oleptro from the MNG as these products are discontinued. Deleted criteria for duloxetine/Cymbalta as it is covered without restriction. Effective 1/1/2019: Updated the STPA criteria to apply to all members without regards to age. Added additional pediatric specific criteria for members less than 12 years of age.
- November 13, 2018: Effective January 1, 2019 Updated coverage table to indicate that Forfivo XL is moved to non-covered for Tufts Health Plan Small Group and Individual Plans. Effective April 1, 2019 move Forfivo XL to not covered for all Tufts Health Plan Large Group Plans.
- September 10, 2019: Administrative update to clarify that the pediatric criteria applies to members 12 years of age and younger. Removed the fluoxetine DR capsules from the step therapy table.
- November 12, 2019: Added Drizalma to the MNG. Administrative update to the step therapy program language to clarify that medications on step therapy may be approved if there is documented contraindication or intolerance to lower step medications.
- July 14, 2020: Effective 10/1/20, moved brand Khedezla to non-covered, and removed from Step-therapy grid. Removed sample exclusion language from coverage criteria and updated sample limitation to the following: Samples, free goods, or similar offerings of the requested medication do not quality for an established clinical response or exception but will be considered on an individual basis for prior authorization.

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.