Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: **Antidepressants**

Effective: January 1, 2025

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☒ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

I. **Antidepressants Step Therapy Program**

The plan has implemented a step therapy program for select antidepressants to encourage the first-line use of lower cost 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, when clinically appropriate.

The following antidepressant medications are managed by step therapy program:

- **Trintellix (vortioxetine)** is indicated for the treatment of major depressive disorder (MDD) in adults.
- **Pexeva (paroxetine mesylate)** is indicated in adults for the treatment of:
  - Major depressive disorder (MDD)
  - Obsessive-compulsive disorder (OCD)
  - Panic disorder (PD)
  - Generalized anxiety disorder (GAD)

II. **Pediatrics Antidepressant Prior Authorization Program**

The goal of the pediatric antidepressant prior authorization program is to encourage the safe prescribing of behavioral health medication regimens to pediatric patients. Select antidepressants that are recommended by clinical guidelines as first-line therapy for pediatrics are covered with no restrictions. Prior authorization is required for all other antidepressants when prescribed to pediatrics12 years of age and younger.

III. **Zurzuvae (zuranolone)**

Zurzuvae (zuranolone) is a neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator indicated for treatment of postpartum depression (PPD) in adults. Zurzuvae can be used alone or as adjunct to oral antidepressant therapy.

Clinical Guideline Coverage Criteria

I. Antidepressant Step Therapy Program:

Note: Prescriptions that meet the initial step therapy requirements will adjudicate **automatically** at the point of service. If the patient 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 for patients who do not meet the step therapy criteria at the point of service.

Drug	Premium	Value	Direct	Core ME	Core NH	Core RI
Step-1						
Citalopram HBr	Covered	Covered	Covered	Covered	Covered	Covered
Escitalopram Oxalate						
Fluoxetine HCL						
Fluvoxamine Maleate						
Paroxetine HCL						
Paroxetine Mesylate Capsules						
Sertraline HCL						
Desvenlafaxine Succinate ER Tablets						
Desvenlafaxine ER 24hr Tablets						
Duloxetine HCL Capsules						
Venlafaxine HCL Tablets						
Bupropion HCL						
Step-2						
Trintellix	Requires prior use of a drug on Step-1 or Step-2				NF	NF
Pexeva	Requires prior use of a drug on Step-1 or Step-2	NF	NF	NF	NF	NF

Automated Step Therapy Coverage Criteria

The following stepped approach applies to coverage of the Step-2 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:

a) The patient has had a trial of one (1) Step-1 or the requested Step-2 medication as evidenced by a previous paid claim under the prescription benefit administered by the plan.

Coverage Criteria for Patients not meeting the Automated Step Therapy Coverage Criteria at the Point of Sale

Step 2: The plan may cover medications on Step-2 if the following criteria are met:

1. Patient has had a trial of a Step-1 or the requested Step-2 medication as evidenced by physician's documented use, excluding the use of samples

OR

2. Patient has a physician documented trial and failure with one, or contraindication or intolerance to all of the step 1 medications

OR

3. Patient was recently started on the requested medication in an acute care setting, residential setting, or partial hospital setting

OR

4. Patient lives in or the prescribing provider's office is located in Maine

II. Pediatrics Antidepressant Prior Authorization Program

The goal of this prior authorization program is to encourage the safe prescribing of behavioral health medication regimens to pediatric patients. A prior authorization is required for pediatric patients 12 years of age and younger who are being prescribed an antidepressant other than those listed in the table below.

Covered (no PA required) antidepressants for pediatrics 12 years of age and younger	
fluoxetine	venlafaxine
fluvoxamine	citalopram
escitalopram	clomipramine
sertraline	imipramine
duloxetine	Fluoxetine-olanzapine

The Plan may authorize coverage of antidepressant medications for patients 12 years of age and younger when the following criteria are met:

1. Documentation that patient had a recent psychiatric hospitalization

OR

2. Documentation that patient has a history of severe risk of harm to self or others

OR

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

OR

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

AND

B) The requested antidepressant is prescribed by a specialist or in consultation with a specialist (psychiatrists, neurologist, etc.) or a developmental pediatrician

III. Zurzuvae (zuranolone)

The plan may authorize coverage of **Zurzuvae (zuranolone)** when all the following criteria are met:

1. ALL of the following:
   a. Documentation of moderate to severe postpartum depression (PPD)

   AND

   b. Documentation that patient is postpartum for 12 months or less at the time of request

   AND

   c. Onset of depressive episode is between 3rd trimester and 4 weeks following delivery, that has been documented by standardized rating scales such as the Beck Depression Scale (BDI), Hamilton Depression Rating Scale (HDRS), Montgomery-Asberg Depression Rating Scale (MADRS), Quick Inventory of 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 patient has not responded adequately to a trial of an oral antidepressant, or clinical rationale that trial of an oral antidepressant is not appropriate due to severity of depression (clinical documentation required)

   OR

2. Patient was recently started on the requested medication in an acute care setting, residential setting, or partial hospital setting

   OR

3. Patient lives in or the prescribing provider's office is located in Maine

Limitations

1. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.
2. 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.
3. If a step 2 antidepressant is requested for a pediatric patient 12 years of age and younger, both the step therapy criteria and the pediatric antidepressant criteria must be met.
4. For Zurzuvae (zuranolone), duration of approval is limited to one 14-day course per postpartum period. Approval will not be authorized in patients who have previously received Zulresso (brexanolone) or Zurzuvae (zuranolone) for the current postpartum depressive episode from the most recent pregnancy.

Codes

None

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Approval And Revision History

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

Subsequent endorsement date(s) and changes made:

- August 8, 2023: No changes.
- January 9, 2024: Added Zurzuvae (zuranolone) for postpartum depression to the Medical Necessity Guideline. Administrative edits made (effective 2/1/2024).
- February 13, 2024: Removed criterion pertaining to patient or prescribing provider’s office is located in Rhode Island (effective 5/1/2024).
- October 8, 2024: Effective January 1, 2025, removed Fetzima, Forfivo XL and Viibryd from the step therapy program.

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.