Pharmacy Medical Necessity Guidelines: Antidepressants

Effective: August 8, 2023

<table>
<thead>
<tr>
<th>Guideline Type</th>
<th>☒ Prior Authorization</th>
<th>☐ Non-Formulary</th>
<th>☒ Step-Therapy</th>
<th>☐ Administrative</th>
</tr>
</thead>
</table>

Applies to:

Commercial Products
- ☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988
- ☒ Tufts Health Plan Commercial products; Fax: 617-673-0988
  CareLinkSM – 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
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.

Antidepressants Step Therapy Program
The following antidepressant medications are managed by step therapy program:
- **Viibryd** (vilazodone hydrochloride) is indicated for the treatment of major depressive disorder (MDD) in adults.
- **Trintellix** (vortioxetine) is indicated for the treatment of major depressive disorder (MDD) in adults.
- **Fetzima** (levomilnacipran hydrochloride) is indicated for the treatment of major depressive disorder (MDD) in adults.
- **Forfivo XL** (bupropion hydrochloride extended-release tablets) is indicated for the treatment of major depressive disorder (MDD), as defined by the Diagnostic and Statistical Manual (DSM).
- **Pexeva** (paroxetine mesylate) is indicated in adults for the treatment of:
  o Major depressive disorder (MDD)
  o Obsessive-compulsive disorder (OCD)
  o Panic disorder (PD)
  o Generalized anxiety disorder (GAD)

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 pediatrics 12 years of age and younger.

Clinical Guideline Coverage Criteria

Antidepressant Prior Authorization 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.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Premium</th>
<th>Value</th>
<th>NH Core</th>
</tr>
</thead>
<tbody>
<tr>
<td>Citalopram HBr</td>
<td>Covered</td>
<td>Covered</td>
<td>Covered</td>
</tr>
<tr>
<td>Escitalopram Oxalate</td>
<td></td>
<td></td>
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<tr>
<td>Fluoxetine HCL</td>
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<tr>
<td>Fluvoxamine Maleate</td>
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<td></td>
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<tr>
<td>Paroxetine HCL</td>
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<td></td>
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<tr>
<td>Paroxetine Mesylate Capsules</td>
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<tr>
<td>Sertraline HCL</td>
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<tr>
<td>Desvenlafaxine Succinate ER Tablets</td>
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<tr>
<td>Desvenlafaxine ER 24hr Tablets</td>
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<td></td>
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<tr>
<td>Duloxetine HCL Capsules</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Venlafaxine HCL Tablets</td>
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<tr>
<td>Bupropion HCL</td>
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</tbody>
</table>

**Step-2**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Premium</th>
<th>Value</th>
<th>NH Core</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viibryd (Vilazodone)</td>
<td>Requires prior use of a drug on Step-1 or Step-2</td>
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<td></td>
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<tr>
<td>Forfivo XL</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Trintellix</td>
<td>Requires prior use of a drug on Step-1 or Step-2</td>
<td>NF</td>
<td></td>
</tr>
<tr>
<td>Fetzima</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pexeva</td>
<td>Requires prior use of a drug on Step-1 or Step-2</td>
<td>NF</td>
<td>NF</td>
</tr>
</tbody>
</table>

**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. The 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. The 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 Rhode Island or Maine

**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      |
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
2. Documentation that patient has a history of severe risk of harm to self or others
3. Documentation that patient is stable on the requested antidepressant for more than 2 months
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

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.

Codes
None

References
11. Fetzima (levomilnacipran) [prescribing information]. Irvine, CA: Allergan USA, Inc.; 2023 May.
24. Prozac (fluoxetine) [prescribing information]. Indianapolis, IN; Lilly USA, LLC.; 2017 November.
25. Prozac Weekly (fluoxetine) [prescribing information]. Indianapolis, IN; Eli Lilly and Company; 2017 December.
27. Sarafem (fluoxetine) [prescribing information]. Fajardo, PR: Warner Chilcott Company, LLC; 2014 October.
31. Trintellix (vortioxetine) [prescribing information]. Lexington, MA: Takeda Pharmaceuticals; 2021 September.

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.

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.