

Effective: February 1, 2024

Guideline Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Non-Formulary <input checked="" type="checkbox"/> Step-Therapy <input type="checkbox"/> Administrative
Applies to:	
Commercial Products	
<input checked="" type="checkbox"/> Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988 <input checked="" type="checkbox"/> Tufts Health Plan Commercial products; Fax: 617-673-0988 CareLink SM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization	
Public Plans Products	
<input checked="" type="checkbox"/> 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:

- **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:
 - 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 pediatrics 12 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	NH Core
Step-1			
Citalopram HBr	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			
Viiibryd (Vilazodone)	Requires prior use of a drug on Step-1 or Step-2		
Forfivo XL	Requires prior use of a drug on Step-1 or Step-2		
Trintellix	Requires prior use of a drug on Step-1 or Step-2		NF
Fetzima	Requires prior use of a drug on Step-1 or Step-2		NF
Pexeva	Requires prior use of a drug on Step-1 or Step-2	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 Rhode Island or 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 Rhode Island or 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

References

1. American Psychiatric Association. Practice guideline for the treatment of patients with major depressive disorder, 3rd edition. 2010 November. URL: psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf. Available from Internet. Accessed 2016 February 19.
2. American Psychiatric Association (APA). Practice guideline for the treatment of patients with obsessive-compulsive disorder. 2007 July. URL: psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/ocd.pdf. Available from Internet. Accessed 2016 February 19.
3. American Psychiatric Association (APA). Practice guideline for the treatment of patients with panic disorder. 2009 January. URL: psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/panicdisorder.pdf. Available from Internet. Accessed 2016 February 19.
4. Anderson IM. Meta-analytical studies on new antidepressants. *Br Med Bull.* 2001;57:161-78.
5. Anderson IM. Selective serotonin reuptake inhibitors versus tricyclic antidepressants: a meta-analysis of efficacy and tolerability. *J Affect Disord.* 2000;58(1):19-36.
6. Bandelow B, Zohar J, Hollander E, et al. World Federation of Societies of Biological Psychiatry (WFSBP) guidelines for the pharmacological treatment of anxiety, obsessive-compulsive and post-traumatic stress disorders—first revisions. *World J Biol Psychiatry.* 2008;9(4):248-312.
7. Donohue JM, Pincus HA. Reducing the societal burden of depression: a review of economic costs, quality of care and effects of treatment. *Pharmacoeconomics.* 2007;25:7.
8. Drizalma Sprinkle (duloxetine) delayed release capsules [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc. ; 2019 July.
9. Dunn JD, Tierney JG. A step therapy algorithm for the treatment and management of chronic depression. *Am J Manag Care.* 2006 Oct;12(12 Suppl):S335-44.
10. Fantino B, Moore N. The self-reported Montgomery-Asberg depression rating scale is a useful evaluative tool in major depressive disorder. *BMC Psychiatry.* 2009;9(26):1-6.
11. Fetzima (levomilnacipran) [prescribing information]. Irvine, CA: Allergan USA, Inc.; 2023 May.
12. Finley PR, Laird LK, Benefiedl, Jr WH. Mood disorders I: major depressive disorders. In: Koda-Kimble MA, Young LY, Kradjan WA, eds. *Applied therapeutics: the clinical use of drugs.* 7th ed. Baltimore: Lippincott Williams & Wilkins; 2001:77.1-37.
13. Fluoxetine drug information. UpToDate [database on the Internet]. Wolters Kluwer. Accessed 2016 August 25.
14. Finley PR, Laird LK, Benefiedl, Jr WH. Mood disorders I: major depressive disorders. In: Koda-Kimble MA, Young LY, Kradjan WA, eds. *Applied therapeutics: the clinical use of drugs.* 7th ed. Baltimore: Lippincott Williams & Wilkins; 2001:77.1-37.
15. Forfivo XL (bupropion) [prescribing information]. Morristown, NJ: Pillar5 Pharma, Inc.; 2019 December.
16. Hansen RA, Gartlehner G, Lohr KN, et al. Efficacy and safety of second-generation antidepressants in the treatment of major depressive disorder. *Ann Intern Med.* 2005;143(6):415-26.
17. Kando JC, Wells BG, Hayes PE. Depressive disorders. In: Dipro JT, Talbert RL, Yee GC et al., eds. *Pharmacotherapy: a pathophysiologic approach.* 5th ed. New York: McGraw-Hill Companies, Inc.; 2002:1243-64.
18. Kessler RC, Berglund P, Demler O, et al. The epidemiology of major depressive disorder: results from the National Comorbidity Survey Replication (NCS-R). *JAMA.* 2003;289(23):3095.
19. Montgomery SA, Asberg M. A new depression scale designed to be sensitive to change. *Br J Psychiatry.* 1979;134:382-9.
20. National Institute for Health and Care Excellence. Depression in adults: recognition and management. 2009 October. URL: <http://www.nice.org.uk/guidance/cg90>. Available from Internet. Accessed 2016 February 19.
21. National Institute for Health and Care Excellence. Depression in children and young people: identification and management. 2015 March. URL: [nice.org.uk/guidance/published?type=cg](https://www.nice.org.uk/guidance/published?type=cg). Available from Internet. Accessed 2016 February 19.
22. Pexeva (paroxetine) [prescribing information]. Roswell, GA: Sabela Pharmaceuticals Inc.; 2021 September.
23. Pristiq (desvenlafaxine) [prescribing information]. Philadelphia, PA: Wyeth Pharmaceuticals Inc.; 2017 November.
24. Prozac (fluoxetine) [prescribing information]. Indianapolis, IN; Lilly USA, LLC.; 2017 March.
25. Prozac Weekly (fluoxetine) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; 2017 December.
26. Rickels K, Athanaisiou M, Robinson D, et al. Evidence for efficacy and tolerability of vilazodone in the treatment of major depressive disorder: a randomized, double-blind, placebo-controlled, trial. *Journal of Clinical Psychiatry.* 2009;70(3):326-33.
27. Sarafem (fluoxetine) [prescribing information]. Fajardo, PR: Warner Chilcott Company, LLC; 2014 October.
28. Sheehan DV, Harnett-Sheehan K, Raj BA. The measurement of disability. *Int Clin Psychopharmacol.* 1996;11(Suppl3):89-95.
29. Soleimani L, Lapidus KAB, Iosifescu DV. Diagnosis and treatment of major depressive disorder. *Neurol Clin.* 2011;29:177-93.
30. Thomas KL, Ellingrod VL. Pharmacogenetics of selective serotonin reuptake inhibitors and associated adverse drug reactions. *Pharmacotherapy.* 2009;29(7):822-31.
31. Trintellix (vortioxetine) [prescribing information]. Lexington, MA: Takeda Pharmaceuticals; 2021 September.
32. Viiibryd (vilazodone) [prescribing information]. Madison, NJ: Allergan, Inc.; 2021 September.
33. Zurzuvae (zuranolone) [package insert]. Cambridge, MA: Sage Therapeutics, Inc and Biogen; November 2023.

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.

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- January 9, 2024: Added Zurzuvae (zuranolone) for postpartum depression to the Medical Necessity Guideline. Administrative edits made (effective 2/1/2024).
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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.