

Policy and Procedure

<p style="text-align: center;">PHARMACY STEP THERAPY POLICY AND CRITERIA ORPTCCNS068.0426</p>	<p style="text-align: center;">CENTRAL NERVOUS SYSTEM DRUGS TRINTELLIX (vortioxetine tablet)</p>
<p>Effective Date: 4/1/2026</p>	<p>Review/Revised Date:</p>
<p>Original Effective Date: 04/26</p>	<p>P&T Committee Meeting Date: 02/26</p>
<p>Approved by: Oregon Region Pharmacy and Therapeutics Committee</p>	

SCOPE:

Providence Health Plan and Providence Health Assurance as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

Commercial

POLICY CRITERIA:**COVERED USES:**

All Food and Drug Administration (FDA)-Approved Indications

REQUIRED MEDICAL INFORMATION:

One of the following:

1. History of use of a generic antidepressant (such as bupropion, citalopram, duloxetine, venlafaxine) within the previous 180 days (verified by pharmacy claims)
2. Inadequate response, intolerance, or contraindication to a generic antidepressant

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS:

Age must be appropriate based on FDA-approved indication

PRESCRIBER RESTRICTIONS: N/A

COVERAGE DURATION:

Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.

QUANTITY LIMIT:

One tablet per day

**PHARMACY STEP THERAPY
POLICY AND CRITERIA
ORPTCCNS068.0426**

**CENTRAL NERVOUS SYSTEM DRUGS
TRINTELLIX (vortioxetine tablet)**

Requests for indications that were approved by the FDA within the previous six (6) months may not have been reviewed by the health plan for safety and effectiveness and inclusion on this policy document. These requests will be reviewed using the New Drug and or Indication Awaiting P&T Review; Prior Authorization Request ORPTCOPS047.

Requests for a non-FDA approved (off-label) indication requires the proposed indication be listed in either the American Hospital Formulary System (AHFS), Drugdex, or the National Comprehensive Cancer Network (NCCN) and is considered subject to evaluation of the prescriber's medical rationale, formulary alternatives, the available published evidence-based research and whether the proposed use is determined to be experimental/investigational.

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

INTRODUCTION:

Vortioxetine is an antidepressant thought to exert its effect through serotonergic reuptake inhibition. It functions as an antagonist at the 5-HT₃ receptor and an agonist at the 5-HT_{1A} receptor.

FDA APPROVED INDICATIONS:

Treatment of major depressive disorder (MDD) in adults

POSITION STATEMENT:

The American Psychological Association (APA) 2019 guidelines for the treatment of depression recommend either psychotherapy or second-generation antidepressants as first line therapy but do not specify preferred agents.²

The Department of Veterans Affairs 2022 clinical practice guidelines recommend bupropion, mirtazapine, serotonin-norepinephrine reuptake inhibitors, selective serotonin reuptake inhibitors, trazodone, vilazodone, and vortioxetine as first-line therapy with no additional preferences.³

REFERENCE/RESOURCES:

1. Trintellix package insert. Lexington, MA: Takeda Pharmaceuticals; 2023 Aug.
2. American Psychological Association. APA Clinical Practice Guideline for the Treatment of Depression Across Three Age Cohorts. <https://www.apa.org/depression-guideline/guideline.pdf> (accessed 2026 Feb 24).
3. U.S. Department of Veterans Affairs. Management of Major Depressive Disorder (MDD) (2022). <https://www.healthquality.va.gov/HEALTHQUALITY/guidelines/MH/mdd/VAD/ODMDDCPGFinal508.pdf> (accessed 2026 Feb 24).