

## POLICY AND PROCEDURE

POLICY NUMBER: *RX.PA.159.E*REVISION DATE: *07/17*

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**POLICY TITLE:** *Viibryd (vilazodone) and Trintellix (vortioxetine)*  
**DEPARTMENT:** *Clinical Pharmacy Services- Utilization Management*  
**ORIGINAL DATE:** *April 2011 (as adopted from UPMC Health Plan)*

**Last P & T Committee Approval Date:** February 2018

**Product Applicability:** *mark all applicable products below:*

|                   |   |                              |  |   |   |
|-------------------|---|------------------------------|--|---|---|
| <b>COMMERCIAL</b> | <input type="checkbox"/> HMO                        | <input type="checkbox"/> PPO | Products: <input type="checkbox"/> Small | Exchange: <input type="checkbox"/> Shop | <input checked="" type="checkbox"/> All |
|                   |   |                              | <input type="checkbox"/> Indiv.          | <input type="checkbox"/> Indiv.         |   |
|                   |   |                              | <input type="checkbox"/> Large           |   |   |
| <b>OTHER</b>      | <input checked="" type="checkbox"/> Self-funded/ASO |                              |  |   |   |

### PURPOSE

The purpose of this policy is to define the prior authorization process for Viibryd (vilazodone) and Trintellix (vortioxetine)

Viibryd (vilazodone), a selective-serotonin receptor reuptake inhibitor and a 5-HT1A receptor partial agonist, is indicated for the treatment of major depressive disorder (MDD).

Trintellix (vortioxetine), a serotonin receptor reuptake inhibitor, a 5-HT3 receptor antagonist, and a 5-HT1A receptor agonist, is indicated for the treatment of major depressive disorder (MDD).

### DEFINITIONS

**MAOI** – a drug in the Monoamine Oxidase Inhibitor class of medications that is FDA-approved to treat major depressive disorder

**SNRI** – a drug in the Serotonin-Norepinephrine Reuptake Inhibitor class of medications that is FDA-approved to treat major depressive disorder

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**SSRI** – a drug in the Selective Serotonin Reuptake Inhibitor class of medications that is FDA-approved to treat major depressive disorder

## **POLICY**

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Viibryd (vilazodone) and Trintellix (vortioxetine), is subject to the prior authorization process.

## **PROCEDURE**

### **Initial Authorization Criteria:**

*Must meet all of the criteria listed below:*

- Must be age 18 years or older
- Must have a diagnosis of major depressive disorder
- Must have chart documentation which shows that the member has failed or has intolerance to at least one drug in each of the following classes:
  - Generic selective serotonin reuptake inhibitor (SSRI)
  - Generic serotonin and norepinephrine reuptake inhibitor (SNRI)
- Must not be on concomitant therapy with a MAOI intended to treat psychiatric disorders.
  - Must not be used within 14 days of stopping a MAOI intended to treat psychiatric disorders.
- Must not be used in combination with linezolid or intravenous methylene blue



**Limitations:**

| Length of Authorization (if above criteria met) |   |
|---|---|
| Initial Authorization                           | Up to duration of member's membership with plan   |
| Reauthorization                                 | N/A   |
| Quantity Level Limit                            |   |
| Viibryd   | <ul style="list-style-type: none"><li>• 1 starter kit per lifetime</li><li>• 30 tablets per 30 days</li></ul> |
| Trintellix                                      | 30 tablets per 30 days  |

If the established criteria are not met, the request is referred to a Medical Director for review.

**REFERENCES**

1. Viibryd [package insert]. New Haven, CT: Trovis Pharmaceuticals LLC.; January 2011.
2. <http://clinicaltrials.gov/ct2/show/NCT00683592>
3. Khan A, Cutler A, Kajdasz D et al. Efficacy and Tolerability of Vilazodone, a Dual-Acting Serotonergic Antidepressant, in the treatment of Patients With Major Depressive Disorder (MDD). Poster NR4-2 presented at the 163rd Annual Meeting of the American Psychiatric Association, May 22-26, 2010, New Orleans, Louisiana. [http://www.clda.com/mediainfo/pdf/P3U-10-0311\\_Vilazodone%208-week%20study\\_Final\\_5.13.10.pdf](http://www.clda.com/mediainfo/pdf/P3U-10-0311_Vilazodone%208-week%20study_Final_5.13.10.pdf) (Accessed 2011 Feb 25).
4. Croft HA, Kajdasz DK, Whalen H et al. The Safety and Tolerability of Vilazodone in Patients With Major Depressive Disorder. Poster 107 presented at the 23rd Annual U.S. Psychiatric and Mental Health Congress; November 18-21, 2010; Orlando, FL. [http://www.clda.com/mediainfo/pdf/P3U-10-1629\\_US%20Psych%20Integ%20Safety\\_F4\\_FINAL\\_11.17.10.pdf](http://www.clda.com/mediainfo/pdf/P3U-10-1629_US%20Psych%20Integ%20Safety_F4_FINAL_11.17.10.pdf). (Accessed 2011 Feb 25).
5. Rickels K, Athanasiou M, Robinson DS et al. Evidence for efficacy and tolerability of vilazodone in the treatment of major depressive disorder: a randomized, double-blind placebo-controlled trial. *J Clin Psych.* 2009;70(3):326-33.
6. Trintellix [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc. and Lundbeck A/S; May 2016
7. American Psychiatric Association (APA). Practice guideline for the treatment of patients with major depressive

**RECORD RETENTION**

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.



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## REVIEW HISTORY

| DESCRIPTION OF REVIEW / REVISION                         | DATE APPROVED                  |
|--|--------------------------------|
| <i>Annual review</i>                                     | <i>02/16, 02/17,<br/>02/18</i> |
| <i>Product name change from Brintellix to Trintellix</i> | <i>06/16</i>                   |
| <i>Criteria Update</i>                                   | <i>07/17</i>                   |

