Clinical Policy: Vortioxetine (Trintellix)

Reference Number: PA.CP.PMN.65
Effective Date: 01/18
Last Review Date: 07/17/19

Coding Implications
Revision Log

Description
Vortioxetine (Trintellix®) is an antidepressant.

FDA approved indication
Trintellix is indicated for the treatment of major depressive disorder.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

It is the policy of Pennsylvania Health and Wellness® that Trintellix is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Depression (must meet all)**:**

1. Diagnosis of major depressive disorder (MDD);
2. Failure of a ≥ 8 week trial of one SSRI at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
3. Failure of a ≥ 8 week trial of one SNRI at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 20 mg/day (1 tablet/day).

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Depression (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or Continuity of Care policy, PA.LTSS,PHAR.01, applies;;
2. Documentation of positive response to therapy;
3. If request is for a dose increase, new dose does not exceed 20 mg/day (1 tablet/day).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or Continuity of Care policy, PA.LTSS,PHAR.01, applies;.

Approval duration: Indefinite or

2. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
MDD: major depressive disorder
SSRI: selective serotonin reuptake inhibitor
SNRI: serotonin norepinephrine reuptake inhibitor

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Major depressive disorder	10 md daily then increased to 20 mg/day as tolerated	20 mg/day

VI. Product Availability

Immediate release tablet: 5 mg, 10 mg, 20 mg

VII. References

1. Trintellix Prescribing Information. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; April 2017. Available at http://www.trintellix.com. Accessed April 11, 2018.
2. Monograph for Trintellix. Clinical Pharmacology. Accessed April 11, 2018. http://www.clinicalpharmacology-ip.com.
3. American Psychiatric Association: Practice guideline for the treatment of patients with major depressive disorder, third edition, 2010. Available at http://psychiatryonline.org/guidelines.aspx. Accessed April 11, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2018 annual review: no significant changes; references reviewed and updated.	08/18	
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07/17/19	