Clinical Policy: Vortioxetine (Trintellix)
Reference Number: AZ.CP.PHAR.10.11.20
Effective Date: 06.17
Last Review Date: 09.12.18
Line of Business: Arizona Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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 health plans affiliated with Centene Corporation® 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. Failure of one SSRI or SNRI used adjunctively with one of the following: bupropion, mirtazapine, or tricyclic antidepressant (TCA) unless contraindicated
5. Dose does not exceed 20 mg/day (1 tablet/day).

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to 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 Centene benefit or member has previously met initial approval criteria;
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 health plan benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to 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 – 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

Appendix B: General Information
Trintellix is pharmacologically distinct from other antidepressants in that it has a combination of inhibiting serotonin reuptake, antagonizes serotonin 5-HT3 receptors and is an agonist for 5-HT1A receptors. The clinical benefit of this mechanism of action is unknown.

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.; Revised April 2017. Available at https://us.trintellix.com/v2 . Accessed March 27, 2018.
2. Clinical Pharmacology [database online]. Tampa, FL Elsevier: Gold Standard, Inc.; 2018. Available http://www.clinicalpharmacology-ip.com/ Accessed March 2018
3. Stahl, Stephen. Stahl's Essential Psychopharmacology Prescriber's Guide Fifth Edition Cambridge University Press Published 2014
4. 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 March 14, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Reformat into new template; References updated	03.18	04.18
Reviewed and updated for AZ.	09.12.18	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.