

## **Clinical Policy: Vortioxetine (Trintellix)**

Reference Number: CP.PMN.65

Effective Date: 05.01.15

Last Review Date: 08.18

Line of Business: HIM, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### **Description**

Vortioxetine (Trintellix<sup>®</sup>) is an antidepressant

### **FDA Approved Indication(s)**

Trintellix is indicated for the treatment of major depressive disorder.

### **Policy/Criteria**

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> 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;
2. Age  $\geq$  18 years;
3. Failure of a  $\geq$  8 week trial of one SSRI at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
4. Failure of a  $\geq$  8 week trial of one SNRI at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 20 mg/day (1 tablet/day).

**Approval duration: 12 months**

### **B. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

## **II. Continued Therapy**

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

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively 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 Centene benefit and documentation supports positive response to therapy.  
**Approval duration: Duration of request or 12 months (whichever is less);** or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

**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 policies – HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration

MAOI: monoamine oxidase inhibitor

SSRI: selective serotonin reuptake inhibitor

SNRI: serotonin norepinephrine reuptake inhibitor

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
<i>SSRI</i>		
citalopram (Celexa <sup>®</sup> )	20 mg PO QD; may increase to 40 mg PO QD after one week	40 mg/day (≤ 60 years) 20 mg/day (> 60 years)
escitalopram (Lexapro <sup>®</sup> )	10 mg PO QD; may increase to 20 mg PO QD after 1 week	20 mg/day
fluoxetine (Prozac <sup>®</sup> , Prozac Weekly <sup>®</sup> )	Prozac: 20 mg PO QD; may increase by 10-20 mg after several weeks  Prozac Weekly: 90 mg PO q week beginning 7 days after the last daily dose	Prozac: 80 mg/day  Prozac Weekly: 90 mg/week
paroxetine (Paxil <sup>®</sup> , Paxil CR <sup>®</sup> , Pexeva <sup>®</sup> )	Paxil, Pexeva: 20 mg PO QD; may increase by 10 mg every week as needed  Paxil CR: 25 mg PO QD; may increase by 12.5 mg every week as needed	Paxil, Pexeva: 50 mg/day  Paxil CR: 62.5 mg/day
sertraline (Zoloft <sup>®</sup> )	50 mg PO QD; may increase every week as needed	200 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
<i>SNRI</i>		
duloxetine (Cymbalta <sup>®</sup> )	20 mg PO BID or 30 mg PO BID or 60 mg PO QD	120 mg/day
venlafaxine (Effexor <sup>®</sup> , Effexor XR <sup>®</sup> )	Effexor: 75 mg/day PO in 2-3 divided doses; may increase by 75 mg every 4 days as needed  Effexor XR: 75 mg PO QD; may increase by 75 mg every 4 days as needed	Effexor: 225 mg/day (outpatient) or 375 mg/day (inpatient)  Effexor XR: 225 mg/day
desvenlafaxine (Pristiq <sup>®</sup> , Khedezla <sup>®</sup> )	50 mg PO QD	400 mg/day
Fetzima <sup>®</sup> (levomilnacipran)	20 mg PO QD for 2 days, then 40 mg PO QD; may increase by 40 mg every 2 days	120 mg/day

*Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) when the drug is available by both brand and generic.*

*Appendix C: Contraindications*

- Trintellix has a black box warning for suicidal thoughts and behaviors

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
Major depressive disorder	10 mg orally 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
Initial guideline creation	08.15	08.15
References updated to reflect current literature search Initial criteria: added diagnosis of depression. Added bullet point#A to renewal criteria.	02.16	05.16

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Added Max FDA approved dose 20mg/day to initial and renewal criteria.		
Changed name from Brintellix to Trintellix; revised criteria to require the use of SSRIs and SNRIs; changed criteria to a require $\geq 8$ week trial each of a SSRI AND a SNRI.	06.16	08.16
Removed age requirement, age is not an absolute contraindication. Added max dose and updated references	03.17	08.17
3Q 2018 annual review: combined HIM (HIM.PA.136) and Medicaid; no significant changes added age to Medicaid; references reviewed and updated.	04.11.18	08.18

**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.

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**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.

**For Health Insurance Marketplace members**, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.

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