

Clinical Policy: Vilazodone (Viibryd)

Reference Number: CP.PMN.145

Effective Date: 08.01.12

Last Review Date: 08.19

Line of Business: HIM, Medicaid

[Revision Log](#)

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

Description

Vilazodone (Viibryd[®]) is an antidepressant.

FDA Approved Indication(s)

Viibryd 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[®] that Viibryd 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 40 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 40 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 [®])	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 [®])	10 mg PO QD; may increase to 20 mg PO QD after 1 week	20 mg/day
fluoxetine (Prozac [®] , Prozac Weekly [®])	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 [®] , Paxil CR [®] , Pexeva [®])	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 [®])	50 mg PO QD; may increase every week as needed	200 mg/day
<i>SNRIs</i>		

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
duloxetine (Cymbalta [®])	20 mg PO BID or 30 mg PO BID or 60 mg PO QD	120 mg/day
venlafaxine (Effexor [®] , Effexor XR [®])	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 [®] , Khedeza [®])	50 mg PO QD	400 mg/day
Fetzima [®] (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[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

Appendix C: Contraindications / Boxed Warnings

- Contraindication(s): Concomitant use of monoamine oxidase inhibitors (MAOIs), or use within 14 days of stopping MAOIs
- Boxed warning(s): suicidal thoughts and behaviors in patients aged 24 years and younger. Safety and effectiveness of vilazodone have not been established in pediatric patients.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Major depressive disorder	10 mg orally daily for 7 days, followed by 20 mg once daily	40 mg per day

VI. Product Availability

Tablet: 10 mg, 20 mg, 40 mg

VII. References

1. Viibryd Prescribing Information. Irvine, CA. Allergan USA, Inc.; May 2018. Available at <https://www.viibryd.com/>. Accessed June 3, 2019.
2. Vilazodone Monograph. Clinical Pharmacology. <http://www.clinicalpharmacology-ip.com>. Accessed June 3, 2019.
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
Clarified trial and failure criteria. Added the following note to address trial and failure criteria update: Trial and failure of two	05.14	05.14

Reviews, Revisions, and Approvals	Date	P&T Approval Date
monotherapy drug regimens with SSRI's will meet criteria. In the event of significant drug adverse event, the time restriction can be overridden. References updated to reflect current literature search.		
Clarified MAOI use contraindication as part of criteria.	05.15	05.15
Converted to new template. Updated description to include proposed mechanism, updated indication to reflect prescribing information. Clarified criteria for approval. Changed an adequate trial from 8 weeks to 4 weeks. Changed step therapy to include two SSRI monotherapy trials OR an SSRI/SNRI with adjunctive therapy. Added dosing recommendations to special instructions.	08.15	08.15
Modified trial period for first line agents, SSRI, SNRI or combination treatment, from ≥ 4 weeks to ≥ 8 weeks.	11.15	11.15
Updated reference to reflect current literature search; Added age criteria for Viibryd since only FDA approved for adult use; Modified Background section to include details of mechanism of action; Updated initial criteria to include appropriate screening of drug to drug integration with MAOI therapy due to absolute contraindication with Viibryd; Updated renewal criteria to include bullet point #A.	02.16	05.16
Modified criteria to require the use of generic trials of 1 SSRIs and 1 SNRIs; removed MAOI safety information; updated references.	07.16	08.16
Removed age requirement, as age is not an absolute contraindication. Updated references.	03.17	08.17
3Q 2018 annual review: policies combined for Medicaid (CP.PPA.16) and HIM (HIM.PA.135) lines of business; no significant changes; Medicaid: added age; references reviewed and updated.	04.11.18	08.18
3Q 2019 annual review: no significant changes; added contraindications and boxed warnings; references reviewed and updated.	06.03.19	08.19

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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