Clinical Policy: Vilazodone (Viibryd)

Reference Number: PA.CP.PMN.145
Effective Date: 10.17.18
Last Review Date: 07/17/19

Revision Log

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 PA Health & Wellness® that Viibryd is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Depression (must meet 1 through 4, or 5)**:**

1. Diagnosis of major depressive disorder;
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; and
4. Dose does not exceed 40 mg/day (1 tablet/day); or
5. Member is currently receiving Viibryd and is responding positively to therapy.

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

II. Continued Therapy

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
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 Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

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 – PA.CP.PMN.53.

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
SSRI		
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
SNRIs		
duloxetine (Cymbalta®)	20 mg PO BID or 30 mg PO BID or 60 mg PO QD	120 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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®, Khedezla®)	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

- Viibryd 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 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.; January 2017. Available at https://www.viibryd.com/. Accessed April 11, 2018.
2. Vilazodone Monograph. 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
Policy Created	10/18	
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07/17/19	