Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 11/01/2018**
Policy Number: PA.CP.PPA.16	**Effective Date: 10/17/2018** **Revision Date: 10/17/2018**
Policy Name: Vilazodone (Viibryd)	**HC Approval Date:**

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review – No Revisions**
- ☐ **Attestation of HC PARP Policy –** *This option should only be used during Readiness Review for Community HealthChoices. The policy must be identical to the PARP approved policy for the HealthChoices Program, with the exception of revisions/clarifications adding the term "Community HealthChoices" to the policy.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

This policy is being retired and replaced by the following policy:

PA.CP.PMN.145 vilazodone (Viibryd)

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:**

Clinical Policy: Vilazodone (Viibryd)

Reference Number: PA.CP.PPA.16
Effective Date: 01/18
Last Review Date: 11/17 Revision Log
Line of Business: Medicaid

Description
Vilazodone (Viibryd®) is an antidepressant.

FDA approved indication
Viibryd is indicated for the treatment of major depressive disorder (MDD).

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 Viibryd is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Depression (must meet 1-4 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;
4. Dose does not exceed 40 mg/day (1 tablet/day).
5. Participants started and stabilized on medication prior to receiving benefits from PAH&W.

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 the 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 40 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 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 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 mg 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 March 2017.
2. Vilazodone Monograph. Clinical Pharmacology. Accessed July 2016. 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 March 10, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date