CENTENE Corporation

PRIOR AUTHORIZATION GUIDELINE

DEPARTMENT: Pharmacy	**DOCUMENT NAME:** vilazodone (Viibryd®)
PAGE: 1 of 3	**REFERENCE NUMBER:** NH.PPA.16
EFFECTIVE DATE: 08/12	**REPLACES DOCUMENT:**
RETIRED:	**REVIEWED:** 05/16, 03/17
PRODUCT TYPE: Medicaid	**REVISED:** 08/14, 7/15, 8/15

IMPORTANT REMINDER

This Clinical Policy has been developed by appropriately experienced and licensed health care professionals based on a thorough review and consideration of generally accepted standards of medical practice, peer-reviewed medical literature, government agency/program approval status, and other indicia of medical necessity.

The purpose of this Clinical Policy is to provide a guide to medical necessity. Benefit determinations should be based in all cases on the applicable contract provisions governing plan benefits ("Benefit Plan Contract") and applicable state and federal requirements, as well as applicable plan-level administrative policies and procedures. To the extent there are any conflicts between this Clinical Policy and the Benefit Plan Contract provisions, the Benefit Plan Contract provisions will control.

Clinical policies are intended to be reflective of current scientific research and clinical thinking. This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding results. 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.

Description: Vilazodone is a novel oral antidepressant that is unrelated to tricyclic or tetracyclic antidepressants. The drug enhances serotonergic activity via a dual mechanism.

Brand: vilazodone (Viibryd®): 10 mg, 20 mg, 40 mg tablets

FDA Labeled Indications: Treatment of mood and anxiety disorders including, but not limited to major depression.

Criteria for Approval:

A. Age of 18 years or greater.
B. Trial and failure of two preferred agents.
C. Clinically unacceptable risk with a change in therapy to a preferred drug

Approval: Initial Approval: 12 months.
Continued Approval: 12 months.

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Special Instructions
➢ Vilazodone is contraindicted for use along with a MAOI or within 14 days of initiation or termination of a MAOI. ➢ There is an increased risk of bleeding while on vilazodone. Caution should be exercised with prescribing along with NSAIDs, warfarin and aspirin. ➢ Preganancy Category C. ➢ Vilazodone should be used cautiously in patients with a history of bipolar disorder (mania or hypomania). ➢ Vilazodone is metabolized extensively by the liver.

References:

1. Viibryd® prescribing information. Accessible at http://www.frx.com/pi/viibryd_pi.pdf .
2. Vilazodone drug monograph. Clinical Pharmacology. Accessed 6/2012.

Revision Log	
Revision	**Date**
Clarified trail and failure criteria.	08/14
Added the following note to address trial and failure criteria update: Trial and failure of two monotherapy drug regimens with SSRI's will meet criteria. In the event of significant drug adverse event, the time restriction can be overridden.	08/14
Added Clinically unacceptable risk with a change in therapy to a preferred drug	07/15
Added the following language to FDA Labeled Indications: "mood disorders including, but not limited to"	08/15
Removed 8 week drug trial length requirement from "Criteria for Approval" under items C and D.	08/15
Annual Review, No Changes	05/16
Annual Review, No Changes	03/17

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POLICY AND PROCEDURE APPROVAL

Pharmacy & Therapeutics Committee: Approval on file

V.P., Pharmacy Operations: Approval on file

Sr. V.P., Chief Medical Officer: Approval on file