

Vilazodone (Viibryd)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Vilazodone (Viibryd) is an antidepressant belonging to the indolalkylamine class indicated for the treatment of major depressive disorder (MDD) in adults. It is a combined selective serotonin-reuptake inhibitor (SSRI) and serotonin type 1A (5-hydroxytryptamine [5-HT_{1A}]) receptor partial agonist. Major depressive disorder is a mental health disorder that causes symptoms of sadness, hopelessness, and loss of interest in things. It can disrupt relationships and everyday activities, such as work, school, and activities that are usually pleasant. There are many medications from several classes that are available to treat major depressive disorder including selective serotonin-reuptake inhibitors (SSRIs), serotonin- and norepinephrine-reuptake inhibitors (SNRIs), tricyclic antidepressants, monoamine oxidase (MAO) inhibitors, and other antidepressants (e.g., bupropion, mirtazapine, trazodone).

Definitions

“Major depressive disorder”, also known as **(MDD)**, is a psychiatric condition characterized by persistent low mood, low energy, or loss of interest in enjoyable activities causing substantial impairment in daily life. MDD is thought to be caused by a combination of genetic, environmental and psychological factors. Risk factors include family history, major life changes, certain medications, chronic health problems, and substance use disorders.

“Neurotransmitter” is a molecule that sends signals from neurons to different parts of the body (e.g., muscles).

Medical Necessity Criteria for Initial Authorization

The Plan considers **vilazodone (Viibryd)** medically necessary when **ALL** of the following criteria are met:

1. The member is 18 years of age or older; **AND**
2. The member has a diagnosis of major depressive depression (MDD); **AND**
3. The member is unable to use or has adequately tried and failed a minimum **ONE** (1) month trial of at least **THREE** (3) therapies, from at least **THREE** (3) of the following classes:
 - a. Noradrenergic and dopaminergic antidepressants (bupropion); **and/or**
 - b. Noradrenergic and specific serotonin antidepressants (e.g., mirtazapine); **and/or**
 - c. Selective serotonin reuptake inhibitors (e.g., citalopram, escitalopram, fluoxetine, paroxetine, sertraline); **and/or**
 - d. Serotonin-norepinephrine reuptake inhibitors (e.g., duloxetine, venlafaxine IR/ER); **and/or**
 - e. Tricyclic antidepressants (e.g., amitriptyline, nortriptyline); **AND**
4. Clinical chart documentation is provided for review to substantiate the above listed requirements.

If the above prior authorization criteria are met, vilazodone (Viibryd) will be approved for 12-months.

Medical Necessity Criteria for Reauthorization

Reauthorization for 12-months will be granted if recent chart documentation (within the last 12-months) shows the member has experienced therapeutic response to the requested medication as evidenced by **ONE** (1) of the following:

1. clinical improvement (e.g., reduction in signs and symptoms, including residual symptoms) in symptoms since starting the requested medication; **OR**
2. stability in condition (e.g., restoration of prior level of psychosocial and occupational function) since starting the requested medication.

Experimental or Investigational / Not Medically Necessary

Vilazodone (Viibryd) for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Bipolar Disorder (BD)
- Generalized Anxiety Disorder
- Post Traumatic Stress Disorder (PTSD)
- Separation Anxiety Disorder
- Social Anxiety Disorder (SAD)

References

1. American Psychiatric Association: Practice Guideline for the Treatment of Patients with Major Depressive Disorder, 3rd edition, 2010. Available at: https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf. Published October 2010. Accessed July 25, 2022.
2. Balt S and Puzantian T. Four Newer Antidepressants: Should You Use Them? The Carlat Psychiatry Report, April 2016. Volume 14, Issue 4.
3. Bauer M, Severus E, Köhler S, Whybrow PC, Angst J, Möller HJ; WFSBP Task Force on Treatment Guidelines for Unipolar Depressive Disorders. World Federation of Societies of Biological Psychiatry (WFSBP) guidelines for biological treatment of unipolar depressive disorders. Part 2: maintenance treatment of major depressive disorder-update 2015. World J Biol Psychiatry. 2015;16(2):76-95. doi: 10.3109/15622975.2014.1001786.
4. Bauer M, Whybrow PC, Anst J, et al. World Federation of Societies of Biological Psychiatry (WFSBP) Guidelines for Biological Treatment of Unipolar Depressive Disorders, Part 2: Maintenance treatment of major depressive disorder and treatment of chronic depressive disorders and subthreshold depressions. World J Biol Psychiatry. 2002;3(2):69-86.
5. Fava M. Prospective studies of adverse events related to antidepressant discontinuation. J Clin Psychiatry. 2006;67(Suppl 4):14-21.

6. Gitlin M. When First-Line Depression Treatments Don't Cut It: Newer Antidepressants and Sometimes, Antipsychotics. *The Carlat Psychiatry Report*, July 2017. Volume 15, Issue 7&8.
7. Guideline Development Panel for the Treatment of Depressive Disorders. Summary of the clinical practice guideline for the treatment of depression across three age cohorts. *Am Psychol*. 2022 Sep;77(6):770-780. doi: 10.1037/amp0000904. Epub 2021 Nov 29. PMID: 34843274.
8. Hirsch M, Birnbaum RJ. Discontinuing antidepressant medications in adults. *Post TW*, ed. UpToDate. Waltham, MA: UpToDate Inc. <http://www.uptodate.com>. Accessed June 26, 2022.
9. McQuaid JR, Buelt A, Capaldi V, et al. The Management of Major Depressive Disorder: Synopsis of the 2022 U.S. Department of Veterans Affairs and U.S. Department of Defense Clinical Practice Guideline. *Ann Intern Med*. 2022 Oct;175(10):1440-1451. doi: 10.7326/M22-1603. Epub 2022 Sep 20. PMID: 36122380.
10. National Collaborating Centre for Mental Health (NCCMH). *Depression: The Treatment and Management of Depression in Adults (Updated Edition)*. National Institute for Health & Clinical Excellence (NICE). 2010.
11. Puzantian T and Carlat DJ. *General Prescribing Tips: Treatment Algorithm for Depression. Medication Fact Book for Psychiatric Practice, 5th edition, 2020*. Newburyport, MA; Carlat Publishing, p27-32.
12. Qaseem A, Owens DK, Etzeandia-Ikobaltzeta I, Tufte J, Cross JT Jr, Wilt TJ; Clinical Guidelines Committee of the American College of Physicians; Crandall CJ, Balk E, Cooney TG, Fitterman N, Hicks LA, Lin JS, Maroto M, Obley AJ, Tice JA, Yost J. Nonpharmacologic and Pharmacologic Treatments of Adults in the Acute Phase of Major Depressive Disorder: A Living Clinical Guideline From the American College of Physicians. *Ann Intern Med*. 2023 Feb;176(2):239-252. doi: 10.7326/M22-2056. Epub 2023 Jan 24. Erratum in: *Ann Intern Med*. 2023 Aug;176(8):1143-1144. doi: 10.7326/L23-0246. PMID: 36689752.
13. Sambunaris, A et al. Efficacy of levomilnacipran extended-release in improving functional impairment associated with major depressive disorder. *International Clinical Psychopharmacology*. 2014; 29(4): p197-205. doi: 10.1097/YIC.0000000000000033.
14. *Treatment and Management of Mental Health Conditions During Pregnancy and Postpartum: ACOG Clinical Practice Guideline No. 5*. *Obstetrics & Gynecology* 141(6):p 1262-1288, June 2023. | DOI: 10.1097/AOG.0000000000005202
15. Viibryd (vilazodone) [prescribing information]. North Chicago, IL: AbbVie Inc; October 2023.
16. Viibryd (vilazodone) [prescribing information]. Madison, NJ: Allergan USA Inc; August 2023.

Clinical Guideline Revision / History Information

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