Oscar Clinical Guideline: desvenlafaxine succinate ER (PG072, Ver. 5)

desvenlafaxine succinate ER

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

Major depressive disorder (MDD), a severe mood disorder, is characterized by a persistent sense of sadness, a lack of interest in activities previously enjoyed, and various physical and mental problems. The symptoms are significant enough to impair daily activities, such as work, school, social interactions, or relationships. Although the precise cause of MDD remains unknown, it's postulated to result from a combination of genetic, biological, environmental, and psychological factors.

Vasomotor symptoms, including hot flashes and night sweats, are among the primary complaints of postmenopausal women and those experiencing menopause due to breast cancer treatment. These symptoms result from fluctuating hormone levels during the menopausal transition and can drastically affect a woman's quality of life, impacting sleep, mood, and overall daily functionality.

Desvenlafaxine succinate extended-release (Pristiq), an SNRI (serotonin-norepinephrine reuptake inhibitor), is indicated for the treatment of adults with major depressive disorder (MDD).

- For major depressive disorder, desvenlafaxine is a valuable treatment option alongside alternatives such as SSRIs, other SNRIs, bupropion, mirtazapine, or tricyclic antidepressants.
- Desvenlafaxine also has recommended use in the management of vasomotor symptoms associated with menopause. It is an important non-hormonal option when other alternatives such as gabapentin, pregabalin, clonidine, or other SSRIs and SNRIs have failed. It offers a way to manage these symptoms effectively, potentially improving the quality of life for postmenopausal women and those experiencing iatrogenic menopause due to breast cancer treatment.

Definitions

"Major depressive disorder" is a psychiatric condition characterized by a persistent sense of despair, reduced energy, and a diminished interest in pleasurable activities, causing significant interference in daily life. MDD is believed to arise from a blend of genetic, environmental, and psychological factors. Risk factors encompass family history, major life changes, certain medications, chronic health issues, and substance abuse disorder

"**Metabolite**" is the substance produced when the body breaks down a drug. The effects of active metabolites are similar to the original drug.

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

Medical Necessity Criteria for Authorization

The Plan considers **desvenlafaxine succinate ER** medically necessary when **ALL** the following criteria are met for the applicable indication listed below:

For the treatment of major depressive disorder

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 **TWO** (2) different formulary alternatives from below, for at least 1 month each:
    a. Selective serotonin reuptake inhibitors (SSRIs)**; *and/or***
    b. Other Serotonin-norepinephrine reuptake inhibitors (SNRIs)**; *and/or***
    c. Bupropion (IR, SR, or XL)**; *and/or***
    d. Mirtazapine**; *and/or***

e. Tricyclic antidepressants (such as amitriptyline, amoxapine, and desipramine)***; AND***

4. Chart documentation is provided for review to substantiate the above listed requirements.

For the management of vasomotor symptoms associated with menopause

1. The medication is being requested for the treatment of vasomotor symptoms in a postmenopausal woman **OR** a woman experiencing iatrogenic menopause due to breast cancer treatment***; AND***
2. The member has contraindications to hormonal therapy, is not able to tolerate hormonal therapy, or prefers not to use hormonal therapy***; AND***
3. The member is unable to use, or has tried and failed ALL of the following:
    a. Nonhormonal alternatives such as: gabapentin, pregabalin, or clonidine***; and/or***
    b. Selective serotonin reuptake inhibitors (SSRIs) (e.g., escitalopram, paroxetine, sertraline)***; and/or***
    c. Other serotonin-norepinephrine reuptake inhibitors (SNRIs) (e.g., duloxetine, venlafaxine)***; AND***
4. Chart documentation is provided for review to substantiate the above listed requirements.

If the above prior authorization criteria are met, desvenlafaxine ER will be approved for 12 months.

Experimental or Investigational / Not Medically Necessary

Desvenlafaxine succinate ER for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven

Appendix

Vasomotor Symptoms Associated With Menopause

Hormone suppression, brought about by menopause or through treatments such as surgery or chemotherapy, often triggers hot flashes. These symptoms are not life-threatening but can impact the quality of life and daily activities. Long-term estrogen use, which had been a common treatment for menopause-associated vasomotor symptoms, has declined due to its association with increased risk of breast cancer, coronary heart disease, stroke, and venous thromboembolism. This prompts the need for alternative therapies like desvenlafaxine.

1. Desvenlafaxine has been shown to be a viable alternative for managing vasomotor symptoms associated with menopause, particularly in patients unable or unwilling to use hormonal therapy. It is recommended as an effective alternative to hormonal therapy by the Endocrine Society, the

North American Menopause Society (NAMS), and the American Cancer Society/American Society of Clinical Oncology (ACS/ASCO).

2. Meta-analyses and controlled trials have shown significant reduction in the frequency and severity of hot flashes among postmenopausal patients using desvenlafaxine compared to placebo.
    a. These improvements were observed as early as one week into treatment. However, higher rates of discontinuation due to adverse events were also reported in desvenlafaxine groups.
    b. The use of desvenlafaxine is not associated with an increased risk of ischemic cardiovascular events, cerebrovascular events, and hepatic events according to a one-year safety assessment.

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Clinical Guideline Revision / History Information

Original Date: 11/05/2020 Reviewed/Revised: 10/14/2021, 12/01/2021, 06/23/2022, 06/29/2023