paroxetine 7.5 mg capsule

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.

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Summary

Vasomotor symptoms (VMS), including hot flashes and night sweats, are common symptoms of menopause that can significantly impact quality of life. They are caused by the decline in estrogen levels during the menopausal transition. Systemic menopausal hormone therapy (MHT) with estrogen, with or without progestin, is the most effective treatment for VMS. However, MHT may not be appropriate for all women, such as those with a history of breast cancer, cardiovascular disease, venous thromboembolism, a history of stroke, or active liver disease. In November, 2025, the FDA released that they would be beginning the process of removing several boxed warnings from MHT estrogen products - including references to risks of cardiovascular disease, breast cancer and probable dementia. Nonhormonal treatment options for VMS include selective serotonin reuptake inhibitors (SSRIs),serotonin-norepinephrine reuptake inhibitors (SNRIs), and other medications like gabapentin, clonidine and oxybutynin.

Paroxetine capsules are a selective serotonin reuptake inhibitor (SSRI) indicated for the treatment of moderate to severe vasomotor symptoms associated with menopause (VMS). It provides an additional nonhormonal treatment option for women who cannot or choose not to use MHT. The brand Brisdelle is no longer on the market.

Paroxetine capsules have a boxed warning for increased risk of suicidal thoughts and behaviors. Monitor for worsening and emergence of suicidal thoughts and behaviors.

Definitions

"Documentation" refers to written information, including but not limited to:

1. Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses;
2. Prescription claims records, and/or prescription receipts to support prior trials of formulary alternatives.

"Menopause" refers to the point in time 12 months after a woman's last menstrual period, marking the end of the menopausal transition.

"No evidence of" indicates that the reviewer has not identified any records of the specified item or condition within the submitted materials or claims history. In the absence of such evidence, the member is considered eligible. If any evidence of the item or condition is present upon review of the request, the applicant does not qualify.

"Perimenopause" is the menopausal transition, a span of time starting when a woman begins experiencing menstrual irregularity through 12 months after the final menstrual period.

"Postmenopause" refers to the time after menopause has occurred, starting 12 months after the final menstrual period.

"Vasomotor symptoms (VMS)" refer to hot flashes (sensations of heat, sweating, flushing) and night sweats associated with the menopausal transition.

"[s]" indicates state mandates may apply.

Clinical Indications

Medical Necessity Criteria for Clinical Review

General Medical Necessity Criteria

The Plan considers **paroxetine 7.5 mg capsule** medically necessary when **ALL** of the following criteria are met:

1. The member is a menopausal woman; *AND*
2. The member meets **ALL** of the following:
    a. No evidence of concurrent use with monoamine oxidase inhibitors (MAOI) or use within 14 days of MAOI use; *and*
    b. No evidence of use with thioridazine; *and*
    c. No evidence of use with pimozide; *AND*
3. Paroxetine 7.5 mg capsule is being prescribed at a dose and frequency that is within FDA approved labeling **OR** is supported by compendia or evidence-based published dosing guidelines for the requested indication.
    The requested medication is being used within the Plan's Quantity Limit of: 1 capsule per day (30 capsules per 30 days).
4. The member meets the applicable Medical Necessity Criteria for Initial Clinical Review or Subsequent Clinical Review listed below.

Medical Necessity Criteria for Initial Clinical Review

Initial Indication-Specific Criteria

<u>Vasomotor symptoms associated with menopause (VMS)</u>

The Plan considers **paroxetine 7.5 mg capsule** medically necessary when **ALL**of the following criteria are met:

1. The member meets the above General Medical Necessity Criteria; *AND*
2. The member is experiencing moderate to severe vasomotor symptoms.

<u>If the above prior authorization criteria are met, the requested product will be authorized for up to 12-months.</u>[s]

Continued Care

Medical Necessity Criteria for Subsequent Clinical Review

Subsequent Indication-Specific Criteria

Vasomotor symptoms associated with menopause (VMS)

The Plan considers **paroxetine 7.5 mg capsule** medically necessary when **ALL** of the following criteria are met:

1. The member meets the above applicable General Medical Necessity Criteria; *AND*
2. Clinically significant reduction in the frequency and/or severity of VMS from baseline, such as:
    a. Reduction in the frequency of moderate to severe hot flashes; *or*
    b. Reduction in the symptomatic severity of hot flashes; *or*
    c. Improvement in VMS-related quality of life, sleep, or other member-reported outcomes; *AND*
3. There is no evidence of unacceptable toxicity or adverse reactions to paroxetine 7.5 mg capsule.

If the above reauthorization criteria are met, the requested product will be authorized for up to 12-months.[s]

Experimental or Investigational or Unproven / Not Medically Necessary[s]

Paroxetine 7.5 mg capsule for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, unproven or not medically necessary. Non-covered indications include, but are not limited to, the following:

- Use in perimenopausal women (before menopause has been reached), as efficacy and safety have not been established in this population.
- Use for treatment of mild VMS, as pivotal trials only included women with moderate to severe VMS defined as ≥7 moderate to severe hot flashes per day or ≥50 per week.
- Use for psychiatric conditions. Paroxetine capsules are a selective serotonin reuptake inhibitor (SSRI); however, it is not indicated for the treatment of any psychiatric condition. Paroxetine capsules contain a lower dose of paroxetine than that used to treat depression, obsessive compulsive disorder, panic disorder, generalized anxiety disorder, social anxiety disorder, and post-traumatic stress disorder. Those who require paroxetine for treatment of a psychiatric condition should discontinue paroxetine capsules and initiate a paroxetine-containing medication that is indicated for such use.

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