ospemifene (Osphena®)

EOCCO POLICY

Policy Type: PA Pharmacy Coverage Policy: EOCCO049

Description

Ospemifene (Osphena) is an orally administered estrogen agonist and antagonist.

Length of Authorization

- Initial: 12 months
- Renewal: 12 months

Quantity limits

Product Name	Indication	Dosage Form	Quantity Limit
ospemifene (Osphena)	Moderate to severe dyspareunia due to vulvar and vaginal atrophy associated with menopause; Moderate to severe vaginal dryness due to vulvar and vaginal atrophy associated with menopause	60 mg tablets	30 tablets/30 days

Initial Evaluation

I. **Ospemifene (Osphena)** may be considered medically necessary when the following criteria below are met:
   A. A diagnosis of **moderate to severe vaginal dryness; AND**
      1. Member is being treated for vaginal dryness as a symptom of vulvar and vaginal atrophy, due to menopause; **AND**
      2. Treatment with the following has been ineffective, contraindicated, or not tolerated:
         i. One systemic hormone replacement therapy (e.g., estradiol oral tablets, estradiol patch, estradiol injection); **AND**
         ii. One vaginal hormone replacement therapy (e.g., Estring, generic estradiol cream)

II. Ospemifene (Osphena) is an excluded medication when the following criteria below are met:
   A. A diagnosis of **moderate to severe dyspareunia** (difficult or painful sexual intercourse) as a symptom of vulvar and vaginal atrophy, due to menopause

Renewal Evaluation

I. Member has received a previous prior authorization approval for this agent through this health plan or has been established on therapy from a previous health plan; **AND**
II. Member is not continuing therapy based off being established on therapy through samples, manufacturer coupons, or otherwise. If they have, initial policy criteria must be met for the member to qualify for renewal evaluation through this health plan; **AND**
III. Request is for a diagnosis of moderate to severe vaginal dryness; **AND**
IV. Member has exhibited improvement or stability of disease symptoms [e.g., decreased genital dryness, burning, irritation, urinary symptoms of urgency, dysuria, and recurrent UTIs]

Supporting Evidence

I. Genitourinary syndrome of menopause (GSM) is defined as a collection of symptoms and signs caused by hypoestrogenic changes to the labia majora/minora, clitoris, vestibule/introitus, vagina, urethra, and bladder that occur in menopausal patients. The term GSM was introduced by the International Society for the Study of Women's Sexual Health and the North American Menopause Society in 2014 and replaced the term vaginal atrophy (other terms include vulvovaginal atrophy, urogenital atrophy, or atrophic vaginitis).
II. Vaginal atrophy is a direct consequence of the hypoestrogenic state associated with menopause resulting in anatomic and physiologic changes in the genitourinary tract. The North American Menopause Society estimates that 10–40% of menopausal women will experience one or more symptoms of vaginal atrophy. Vaginal atrophy causes bothersome vaginal symptoms commonly associated with menopause including, vaginal or vulvar dryness, discharge, itching, and dyspareunia. A loss of superficial epithelial cells in the genitourinary tract causes thinning of tissue. Loss of vaginal rugae and elasticity occur with a narrowing and shortening of the vagina. Epithelial tissues are more fragile and may tear, leading to bleeding and fissures. There also is a loss of subcutaneous fat in the labia majora. These changes result in narrowing of the introitus, fusion of the labia minora, and shrinking of the clitoral prepuce and urethra. Vaginal pH becomes more alkaline, which may alter the vaginal flora and increase the risk of urogenital infection.
III. American College of Obstetricians and Gynecologist (ACOG) stated in their Clinical Guidelines on Management of Menopausal Symptoms that vaginal symptoms (e.g., dyspareunia, vaginal or vulvar dryness, discharge, itching) are best treated with systemic or topical hormone therapy. These guidelines recommend both systemic and vaginal/local estrogen preparations.
IV. The 2022 hormone therapy position statement of The North American Menopause Society attest hormone therapy remains the most effective treatment for vasomotor symptoms (VMS) and the genitourinary syndrome of menopause and has been shown to prevent bone loss and fracture. The risks of hormone therapy differ depending on type, dose, duration of use, route of

administration, timing of initiation, and whether a progestogen is used. Treatment should be individualized using the best available evidence to maximize benefits and minimize risks, with periodic reevaluation of the benefits and risks of continuing therapy. For bothersome genitourinary syndrome of menopause symptoms not relieved with over-the-counter therapies in women without indications for use of systemic hormone therapy, low-dose vaginal estrogen therapy or other therapies (eg, vaginal dehydroepiandrosterone or oral ospemifene) are recommended.

V. Dyspareunia is defined as difficult or painful sexual intercourse. Ospemifene (Osphena) for dyspareunia, a form of sexual dysfunction is in a category of medications that are not covered under the prescription benefit. Drugs used for sexual dysfunction are excluded from coverage. Please reference the member handbook/certificate of coverage for further information regarding this denial.

References

1. Oregon Insurance Division Bulletin INS 2014-1 Mental Health Parity.
2. Diagnostic and Statistical Manual of Mental Disorders (DSM) Versions IV-TR and V.
3. Osphena [prescribing information]. Shionogi Inc.: Florham Park, NJ; January 2019
4. Gracia C. The American College of Obstetricians and Gynecologist Clinical Guidelines on Management of Menopausal Symptoms. Am Fam Physician. 2014; 90(5):338-340.
5. The 2022 Hormone Therapy Position Statement of The North American Menopause Society" Advisory Panel. The 2022 hormone therapy position statement of The North American Menopause Society. Menopause. 2022;29(7):767-794.

Related Policies

Currently there are no related policies.

Policy Implementation/Update:

Action and Summary of Changes	Date
Updated supporting evidence to reflect new guideline updates from the 2022 hormone therapy position statement of the North American Menopause Society. Updated quantity limit table and renewal criteria to standard formatting.	07/2023
Updated policy to remove coverage in the setting of dyspareunia as this is an excluded benefit.	09/2019
Converted criteria to the new policy format. Added newly FDA approved indication of moderate to severe vaginal dryness due to vulvar and vaginal atrophy associated with menopause. The route for approval in the setting of vaginal dryness follows the ACOG Clinical Guidelines.	03/2019