



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	Dosage Form	Indication	Quantity Limit	DDID
ospemifene (Osphena)	60 mg tablets	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	30 tablets/30 days	178807

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. Ospemifene (Osphena) may be considered medically necessary when the following criteria below are met:



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- 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. Member has experienced symptomatic improvement (e.g., improvement in pain, discomfort, dryness, etc.)
- 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

Supporting Evidence

- I. 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.
- II. Ospemifene (Osphena) is classified as an impotence drug according to First Databank. This is considered a categorical exclusion in the prescription benefit structure; however, coverage is allowed in the setting of moderate to severe vaginal dryness outside of the dyspareunia setting.
- III. 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; March 2018
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.

Policy Implementation/Update:

Date Created	February 2016
Date Effective	February 2016
Last Updated	September 2019
Last Reviewed	03/2019, 09/2019



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Action and Summary of Changes	Date
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