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

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Dosage Form</th>
<th>Indication</th>
<th>Quantity Limit</th>
<th>DDID</th>
</tr>
</thead>
<tbody>
<tr>
<td>ospemifene (Osphena)</td>
<td>60 mg tablets</td>
<td>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</td>
<td>30 tablets/30 days</td>
<td>178807</td>
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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:
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**

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

**Policy Implementation/Update:**

<table>
<thead>
<tr>
<th>Date Created</th>
<th>February 2016</th>
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<tbody>
<tr>
<td>Date Effective</td>
<td>February 2016</td>
</tr>
<tr>
<td>Last Updated</td>
<td>September 2019</td>
</tr>
<tr>
<td>Last Reviewed</td>
<td>03/2019, 09/2019</td>
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<table>
<thead>
<tr>
<th>Action and Summary of Changes</th>
<th>Date</th>
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<tbody>
<tr>
<td>Updated policy to remove coverage in the setting of dyspareunia as this is an excluded benefit.</td>
<td>09/2019</td>
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<tr>
<td>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.</td>
<td>03/2019</td>
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