

Osphena (ospemifene)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Osphena (ospemifene)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Osphena (ospemifene) may be approved for individuals who meet the following criteria:

- I. Individual is using to treat moderate-to-severe dyspareunia , a symptom of vulvar and vaginal atrophy (VVA) due to menopause; **OR**
- II. Individual is using to treat moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause;

AND

- III. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to one preferred low-dose vaginal estrogen product (such as, Premarin (conjugated estrogen) vaginal cream, or Yuvaferm (estradiol) vaginal tablet) (NAMS 2017);

OR

- IV. The preferred vaginal estrogen agent is not acceptable due to the presence of mild to moderate hepatic impairment.

Requests for Osphena (ospemifene) may not be approved for individuals who meet the following criteria:

- I. Individual has undiagnosed abnormal genital bleeding; **OR**
- II. Individual has known or suspected estrogen-dependent neoplasia; **OR**
- III. Individual has active DVT (deep vein thrombosis), PE (pulmonary embolism) or a history of these conditions; **OR**
- IV. Individual has active arterial thromboembolic disease [for example, stroke and myocardial infarctions (MI)] or a history of these conditions.

Note: Osphe[®]na (ospemifene) has black box warnings for endometrial cancer, stroke, and thromboembolic disease. Concomitant progestin therapy should be considered in women with an intact uterus.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL:. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: March 4, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.