MEDICAL MUTUAL®

Drug Policy

Policy:	Osphena (ospemifene)	Annual Review Date: 03/21/2024 Last Revised Date: 03/21/2024

OVERVIEW

Osphena is an estrogen agonist/antagonist with tissue selective effects, commonly referred to as a selective estrogen receptor modulator (SERM) indicated for the treatment of moderate to severe dyspareunia and moderate to severe vaginal dryness, symptoms of vulvar and vaginal atrophy, due to menopause.

POLICY STATEMENT

This policy involves the use of Osphena. Prior authorization is recommended for pharmacy benefit coverage of Osphena. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

Use of Osphena for treatment of sexual dysfunction indications will not be approved on plans with sexual dysfunction therapy coverage exclusions. This includes but may not be limited to treatment of dyspareunia for members of On- and Off-Exchange plans.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Osphena is recommended in those who meet the following criteria:

1. **Moderate to Severe Dyspareunia*, new starts**
   Criteria. *Patient must meet the following criteria*
   - **A.** Patient is a post-menopausal woman with a diagnosis of moderate to severe dyspareunia due to vulvar and vaginal atrophy; AND
   - **B.** Patient has tried and failed a low dose vaginal estrogen preparation (e.g. generic estradiol vaginal cream, generic estradiol vaginal insert, Yuvafem, Premarin vaginal cream, Estrace vaginal cream, Estring, Vagifem); AND
   - **C.** Patient does NOT have any of the following contraindications to Osphena:
     - **a.** Undiagnosed abnormal genital bleeding
     - **b.** Known or suspected estrogen-dependent neoplasm
     - **c.** Active deep vein thrombosis, pulmonary embolism, or a history of these conditions

d. Active arterial thromboembolic disease
e. Hypersensitivity to Osphena or any ingredient
f. Known or suspected pregnancy; AND

D. Osphena will NOT be used with estrogens, estrogen agonist/antagonists, fluconazole, or rifampin; AND
E. The patient does not have hepatic impairment; AND
F. Use of Osphena will be for the shortest duration consistent with treatment goals and risks for the individual woman. Postmenopausal women should be re-evaluated periodically as clinically appropriate to determine if treatment is still necessary; AND
G. Patients will not exceed maximum recommended dose of 60 mg taken once daily with food

2. <u>Moderate to Severe Dyspareunia*, continuation of therapy</u>
Criteria. *Patient must meet the following criteria*

A. The patient continues to meet all criteria for new starts; AND
B. The patient has been evaluated and has seen improvement on Osphena, as determined by the prescriber

3. <u>Moderate to Severe Vaginal Dryness, new starts</u>
Criteria. *Patient must meet the following criteria*

A. The patient is a post-menopausal woman with a diagnosis of moderate to severe vaginal dryness due to vulvar and vaginal atrophy; AND
B. The patient has tried and failed a low dose vaginal estrogen preparation (e.g. generic estradiol vaginal cream, generic estradiol vaginal insert, Yuvafem, Premarin vaginal cream, Estrace vaginal cream, Estring, Vagifem); AND
C. The patient does NOT have any of the following contraindications to Osphena
a. Undiagnosed abnormal genital bleeding
b. Known or suspected estrogen-dependent neoplasm
c. Active deep vein thrombosis, pulmonary embolism, or a history of these conditions
d. Active arterial thromboembolic disease
e. Hypersensitivity to Osphena or any ingredient
f. Known or suspected pregnancy; AND
D. Osphena will NOT be used with estrogens, estrogen agonist/antagonists, fluconazole, or rifampin; AND
E. The patient does not have hepatic impairment; AND
F. Use of Osphena will be for the shortest duration consistent with treatment goals and risks for the individual woman. Postmenopausal women should be re-evaluated periodically as clinically appropriate to determine if treatment is still necessary; AND
G. The patient will not exceed the maximum recommended dose of 60 mg taken once daily

4. <u>Moderate to Severe Vaginal Dryness, continuation of therapy</u>
Criteria. *Patient must meet the following criteria*

A. The patient continues to meet all criteria for new starts (above); AND
B. The patient has been evaluated and has seen improvement on Osphena, as determined by the prescriber

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***Dyspareunia is not an approvable indication for plans with coverage exclusions for sexual dysfunction therapies, including but not limited to, On-Exchange and Off-Exchange health plans.**

Initial Approval/ Extended Approval.
A) *Initial Approval:* 2 months (60 days)
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Osphena has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational, or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Osphena [package insert]. Shionogi Inc. Florham Park, NJ. January 2019.
2. Portman DJ, Bachmann GA, Simon JA; and the Ospemifene Study Group Ospemifene, a novel selective estrogen receptor modulator for treating dyspareunia associated with postmenopausal vulvar and vaginal atrophy.*Menopause* 2013 Jan 28
3. Simon JA, Lin VH, Radovich C, Bachmann GA; The Ospemifene Study Group One-year long-term safety extension study of ospemifene for the treatment of vulvar and vaginal atrophy in postmenopausal women with a uterus. *Menopause* 2012 Nov 8
4. Bachmann GA, Komi JO; Ospemifene Study Group Ospemifene effectively treats vulvovaginal atrophy in postmenopausal women: results from a pivotal phase 3 study. *Menopause* 2010 May-Jun;17(3):480-6
5. Ellis AJ, Hendrick VM, Williams R, Komm BS. Selective estrogen receptor modulators in clinical practice: a safety overview. Expert Opin Drug Saf. 2015 Jun;14(6):921-34
6. Ospemifene. In: DRUGDEX (online database). Truven Health Analytics: Greenwood Village, CO. Last updated 12 August 2023. Accessed 19 March 2024.