

## Clinical Policy: Ospemifene (Osphena)

Reference Number: PA.CP.PMN.168

Effective Date: 10/2018

Last Review Date: 10/2023

[Revision Log](#)

### Description

Ospemifene (Osphena®) is a selective estrogen receptor modulator (SERM).

### FDA Approved Indication(s)

Osphena is indicated for the treatment of moderate to severe dyspareunia and vaginal dryness, symptoms of vulvar and vaginal atrophy, due to menopause.

### Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of PA Health & Wellness® that Osphena is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Dyspareunia or Vaginal Dryness (must meet all):

1. Diagnosis of dyspareunia or vaginal dryness due to menopause;
2. Age  $\geq$  18 years;
3. Failure of two vaginal lubricants or vaginal moisturizers at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;
4. Failure of  $\geq$  4 weeks of one vaginal estrogen (e.g., estradiol vaginal cream, Premarin® vaginal cream) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;
5. Dose does not exceed 60 mg (1 tablet) per day.

**Approval duration:** 12 months

##### B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

#### II. Continued Therapy

##### A. Dyspareunia or Vaginal Dryness (must meet all):

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 60 mg (1 tablet) per day.

**Approval duration:** 12 months

**B. Other diagnoses/indications** (must meet 1 or 2):

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.

**Approval duration: Duration of request or 6 months (whichever is less);** or

2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration

SERM: selective estrogen receptor modulator

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
estradiol vaginal cream (Estrace®)	Initial: 2 to 4 gm vaginally QD for 1 to 2 weeks, gradually reduce to 50% of initial dose for 1 to 2 weeks Maintenance: 1 gm 1 to 3 times a week	Varies
Premarin® (conjugated estrogens) vaginal cream	0.5 gm intravaginally twice per week continuously	Varies
estradiol vaginal tablet (Vagifem®)	1 tablet intravaginally QD for 2 weeks, followed by 1 tablet twice weekly	1 tablet/day
Estring® (estradiol vaginal ring)	2 mg intravaginally for 90 days	2 mg every 90 days
Vaginal lubricants: <u>Water-based</u> Astroglide®, FemGlide®, Just Like Me®, K-Y Jelly®, Pre-Seed®, Slippery Stuff®, Summer's Eve® <u>Silicone-based</u> ID Millennium®, Pink®, Pjur®, Pure Pleasure®	Apply intravaginally before sex	Varies
Vaginal moisturizers:	Apply intravaginally before sex	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Fresh Start <sup>®</sup> , K-Y Silk-E <sup>®</sup> , Moist Again <sup>®</sup> , Replens <sup>®</sup> , K-Y Liquibeads <sup>®</sup>		

*Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) when the drug is available by both brand and generic.*

#### Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): undiagnosed abnormal genital bleeding;
- known or suspected estrogen-dependent neoplasia; active deep vein thrombosis, pulmonary embolism, or a history of these conditions; active thromboembolic disease (for example, stroke and myocardial infarction) or a history of these conditions; hypersensitivity (for example, angioedema, urticaria, rash, pruritis) to Osphe<sup>®</sup> or any ingredients; known or suspected pregnancy
- Box warning(s): endometrial cancer and cardiovascular disorders(stroke and deep vein thrombosis).

#### V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Moderate to Severe Dyspareunia or Vaginal Dryness due to menopause	60 mg PO QD	60 mg/day

#### VI. Product Availability

Tablet: 60 mg

#### VII. References

1. Osphe<sup>®</sup> Prescribing Information. Florham Park, NJ: Shionogi Inc.; January 2019. Available at: <http://www.osphena.com/>. Accessed August 16, 2022.
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3. Pinkerton JV, Aguirre FS, Blake J, et al. The 2017 hormone therapy position statement of The North American Menopause Society. Menopause. 2017;24(7):728-753. doi:10.1097/GME.0000000000000921.
4. Faubion S, Sood R, Kapoor E. Genitourinary Syndrome of Menopause: Management Strategies for the Clinician. Mayo Clin Proc. 2017 Dec;92(12):1842-1849. doi: 10.1016/j.mayocp.2017.08.019.
5. Stuenkel C, Davis S, Gompel A, et al. Treatment of Symptoms of the Menopause: An Endocrine Society Clinical Practice Guideline. The Journal of Clinical Endocrinology & Metabolism, Volume 100, Issue 11, 1 November 2015, Pages 3975–4011, <https://doi.org/10.1210/jc.2015-2236>
6. Vaginal and Vulvar Comfort: Effective Treatments for Sexual Problems. The North American Menopause Society. Available at: <https://www.menopause.org/for-women/sexual-health-menopause-online/effective-treatments-for-sexual-problems>. Accessed July 11, 2023

7. Shifren JL and Gass MLS. The North American Menopause Society recommendations for clinical care of midlife women. *Menopause* 2014;21(10):1-25.
8. Vaginal Dryness. The North American Menopause Society. Available at: <https://www.menopause.org/docs/default-source/for-women/mn-vaginal-dryness.pdf>. Accessed July 11, 2023.
9. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed July 11, 2023.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	10/2018	
Q2 2019 annual review: Criteria added for new FDA indication: treatment of moderate to severe vaginal dryness; references reviewed and updated.	04/2019	
4Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	10/2019	
4Q 2020 annual review: Age limit of 18 years old added, References reviewed and updates.	08/2020	
4Q 2021 annual review: no significant changes; references reviewed and updated.	10/2021	
4Q 2022 annual review: no significant changes; references reviewed and updated.	10/2022	
4Q 2023 annual review: no significant changes; references reviewed and updated.	10/2023	