Clinical Policy: Ospemifene (Osphena)

Reference Number: PA.CP.PMN.168
Effective Date: 10/2018
Last Review Date: 10/2024

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 ≥ 18 years;
3. Failure of two vaginal lubricants or vaginal moisturizers *(see Appendix B for examples)*, unless clinically significant adverse effects are experienced or all are contraindicated;
4. Failure of ≥ 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.PHARM.01) applies;
2. Member is responding positively to therapy (e.g., dyspareunia symptom reduction);
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.PHARM.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 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: *Water-based* Astroglide®, FemGlide®, Just Like Me®, K-Y Jelly®, Pre-Seed®, Slippery Stuff®, Summer's Eve® *Silicone-based* 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®, K-Y Silk-E®, Moist Again®, Replens®, K-Y Liquibeads®		

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) 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 Osphena 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. Osphena Prescribing Information. Florham Park, NJ: Shionogi Inc.; February 2024. Available at: http://www.osphena.com/. Accessed July 17, 2024.
2. American College of Obstetricians and Gynecologists Committee on Practice Bulletins-Gynecology. ACOG Practice Bulletin No. 213: Female sexual dysfunction. Obstet Gynecol. 2019 Jul;134(1):203-205
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 31, 2024.

7. Shifren JL and Gass MLS. The North American Menopause Society recommendations for clinical care of medlife 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 31, 2024.
9. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed July 31, 2024.

Reviews, Revisions, and Approvals	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
4Q 2024 annual review: removed “at up to maximally indicated doses” for vaginal lubricant/moisturizer trial requirement since there are no maximum doses for these products; added an example of positive response to therapy; references reviewed and updated.	10/2024