

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1277-7
Program	Prior Authorization/Notification
Medication	Osphena® (ospemifene)
P&T Approval Date	3/2019, 3/2020, 3/2021, 3/2022, 3/2023, 3/2024, 3/2025
Effective Date	6/1/2025

1. Background:

Osphena (ospemifene) is indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy due to menopause and for the treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy (VVA) due to menopause.

2. Coverage Criteria^a:

A. Initial Authorization

1. Benefit designs covering medications to treat sexual dysfunction
 - a. **Osphena** will be approved based on the following criteria:
 - (1) Diagnosis of **one** of the following:
 - (a) Treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy due to menopause
 - (b) Treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy (VVA) due to menopause.
2. Benefit designs excluding medications to treat sexual dysfunction
 - a. **Osphena** will be approved based on the following criterion:
 - (1) Treatment of moderate to severe vaginal dryness, a symptom of VVA due to menopause

Authorization will be issued for 12 months

B. Reauthorization

1. **Osphena** will be approved based on the following criterion:
 - a. Documentation of positive clinical response to therapy

Authorization will be issued for 12 months

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Supply limits may be in place
- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4. References:

1. Osphena [package insert]. Princeton, NJ: Duchesnay USA, Inc; February 2024.

Program	Prior Authorization/Notification - Osphena
Change Control	
Date	Change
3/2019	New program
3/2020	Annual review. Updated references.
3/2021	Annual review. No changes.
3/2022	Annual review. No changes.
3/2023	Annual review. Added mandate language.
3/2024	Annual review. Updated references.
3/2025	Annual review. Updated references.