

# Initial Prior Authorization

## Osphena

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Osphena	ospemifene

### Indications

#### FDA-approved Indications

Osphena is indicated for:

- The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause.
- The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.

### Coverage Criteria

#### Moderate to Severe Dyspareunia

Authorization may be granted when the requested drug is being prescribed for the treatment of moderate to severe dyspareunia (pain during sexual intercourse) due to menopause.

## Moderate to Severe Vaginal Dryness

Authorization may be granted when the requested drug is being prescribed for the treatment of moderate to severe vaginal dryness due to menopause.

## Continuation of Therapy

### Moderate to Severe Dyspareunia

Authorization may be granted when the requested drug is being prescribed for the treatment of moderate to severe dyspareunia (pain during sexual intercourse) due to menopause when ALL of the following criteria are met:

- The patient has achieved or maintained a positive clinical response to the requested drug.
- The patient has been re-evaluated periodically to determine if treatment is still medically necessary.

### Moderate to Severe Vaginal Dryness

Authorization may be granted when the requested drug is being prescribed for the treatment of moderate to severe vaginal dryness due to menopause when ALL of the following criteria are met:

- The patient has achieved or maintained a positive clinical response to the requested drug.
- The patient has been re-evaluated periodically to determine if treatment is still medically necessary.

## Duration of Approval (DOA)

- 961-A: DOA: 12 months

## References

1. Osphena [package insert]. Princeton, NJ: Duchesnay USA, Inc.; February 2024.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed November 29, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 11/29/2024).