

# PRIOR AUTHORIZATION CRITERIA

**BRAND NAME**  
(generic)

**OSPHERA**  
(ospemifene)

**Status: CVS Caremark® Criteria**  
**Type: Initial Prior Authorization**

## POLICY

### 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 Due to Menopause**

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

#### **Moderate to Severe Vaginal Dryness Due to Menopause**

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

### CONTINUATION OF THERAPY

#### **Moderate to Severe Dyspareunia Due to Menopause**

Authorization may be granted when the requested drug is being prescribed for 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 necessary

#### **Moderate to Severe Vaginal Dryness Due to Menopause**

Authorization may be granted when the requested drug is being prescribed for 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 necessary

### DURATION OF APPROVAL (DOA)

- 961-A: DOA: 12 months

### REFERENCES

1. Osphena [package insert]. Florham Park, NJ: Shionogi Inc.; January 2019.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. <https://online.lexi.com>. Accessed December 05, 2023.

Osphena PA Policy UDR 01-2024.docx

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.

©2023 CVS Health and/or its affiliates. All rights reserved. 106-58428A 021423

3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 12/05/2023).