

PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

OSPHERA
(ospemifene)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization

Ref # 961-A

* Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.

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

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for the treatment of any of the following: A) Moderate to severe dyspareunia (pain during sexual intercourse) due to menopause, B) Moderate to severe vaginal dryness due to menopause

RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Osphena is indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause. Osphena is also indicated for the treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.

REFERENCES

1. Osphena [package insert]. Florham Park, NJ: Shionogi Inc.; January 2019.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. <http://online.lexi.com/>. Accessed December 2020.
3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. <http://www.micromedexsolutions.com/>. Accessed December 2020.

Written by: UM Development (CY)

Date Written: 03/2013

Revised: (RP) 12/2013; (JH) 12/2014, 12/2015 (no clinical changes); (KM) 12/2016 (removed contraindication question), 12/2017 (no clinical changes); (KC) 12/2018 (no clinical changes), 02/2019 (new indication); (JK) 12/2019 (no clinical changes/removed MDC designation from title/document); (CJM) 12/2020 (no clinical changes)

Reviewed: Medical Affairs: (LS) 03/2013; (LB) 12/2013; (MM) 12/2014; (LMS) 12/2016; (TP) 05/2018; (ME) 02/2019; (CHART) 01/02/2020, 12/31/2020

External Review: 04/2013, 04/2014, 04/2015, 04/2016, 04/2017, 06/2018, 04/2019, 04/2020, 04/2021

Osphena PA 961-A 12-2020

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CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed for the treatment of any of the following: A) Moderate to severe dyspareunia (pain during sexual intercourse) due to menopause, B) Moderate to severe vaginal dryness due to menopause?	Yes	No
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Mapping Instructions

Mapping Instructions			
	Yes	No	DENIAL REASONS – DO NOT USE FOR MEDICARE PART D
1.	Approve, 12 months	Deny	<p>You do not meet the requirements of your plan. Your plan covers this drug when you have any of these conditions:</p> <ul style="list-style-type: none"> - Moderate to severe pain during sexual intercourse due to menopause - Moderate to severe vaginal dryness due to menopause <p>Your request has been denied based on the information we have.</p> <p>[Short Description: No approvable diagnosis]</p>