UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Osphena

Program	Prior Authorization
Medication	Osphena (ospemifene)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York Chip, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	3/2019
Pharmacy and Therapeutics Approval Date	3/2020
Effective Date	5/2020

1. Background:

The intent of the criteria is to ensure appropriate utilization of Osphena (ospemifene) for the treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy (VVA), due to menopause.

2. Coverage Criteria:

A. Initial Authorization

1. **Osphena** will be approved based on **both** of the following criteria:
   a. Treatment of moderate to severe vaginal dryness, a symptom of VVA, due to menopause
      NOTE: Treatment of dyspareunia is a benefit exclusion.

-AND-

   b. History of failure, contraindication, or intolerance to **both** of the following:
      - Estradiol vaginal cream
      - Estradiol vaginal tablet

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

3. Additional Clinical Rules:

- 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.
- Supply limits may be in place.

4. References:

1. Osphena [package insert]. Florham Park, NJ: Shionogi Inc.; January 2019.
2. Stuenkel CA, Davis SR, Gompel A, et al. Treatment of symptoms of the menopause: An Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2015; 100(11):3975-4011.

Program	Prior Authorization – Osphena
Change Control	
Date	Change
4/2019	New program
3/2020	Annual review, added Section 3- Additional Clinical Rules.