UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 2242-3
Program	Prior Authorization/Medical Necessity
Medication	Intrarosa® (prasterone)
P&T Approval Date	6/2021, 6/2022, 6/2023
Effective Date	9/1/2023; Oxford only: 9/1/2023

1. Background:

Imvexxy (estradiol) vaginal insert, Intrarosa (prasterone) vaginal insert, Osphena (ospemifene) oral tablet, and Premarin (conjugated estrogens) vaginal cream are indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy (VVA), due to menopause. Osphena is also indicated for the treatment of moderate to severe vaginal dryness, a symptom of VVA, due to menopause and Premarin vaginal cream is indicated for the treatment of atrophic vaginitis and kraurosis vulvae.

2. Coverage Criteria[a]:

A. **Initial Authorization**

1. **Intrarosa** will be approved based on **all** of the following criteria*:

    a. Diagnosis of moderate to severe dyspareunia

    - AND-

    b. Patient has vulvar and vaginal atrophy due to menopause

    -AND-

    c. History of failure, contraindication, or intolerance to **two** of the following:

    1) Imvexxy (estradiol)
    2) Osphena (ospemifene)
    3) Premarin vaginal cream

    Authorization will be issued for 12 months

B. **Reauthorization**

2. **Intrarosa** 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

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management programs may apply.

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.

   ***** Coverage of medications for the treatment dyspareunia is based on benefit design. Please refer to member's specific benefits for coverage determination.

4. **References:**

1. Imvexxy [package insert]. Boca Raton, FL: TherapeuticsMD, Inc.; November 2021.
2. Intrarosa [package insert]. East Hanover, NJ: Millicent U.S. Inc.; November 2020.
3. Osphena [package insert]. Princeton, NJ: Duchesnay USA, Inc.; April 2023.
4. Premarin cream [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals LLC; September 2019.
5. The 2020 genitourinary syndrome of menopause position statement of The North American Menopause Society. *Menopause: The Journal of The North American Menopause Society*. 2020: 27(9); 976-92.

Program	Prior Authorization/Medical Necessity - Intrarosa
Change Control	
Date	Change
6/2021	New program
6/2022	Annual review. Updated references.
6/2023	Annual review. Updated references & realigned numbering.

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