UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2242-4
Program	Prior Authorization/Medical Necessity
Medication	Intrarosa® (prasterone)
P&T Approval Date	6/2021, 6/2022, 6/2023, 6/2024
Effective Date	9/1/2024

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**

1. **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 management programs may apply.

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

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. Imvexxy [package insert]. Boca Raton, FL: TherapeuticsMD, Inc.; November 2023.
2. Intrarosa [package insert]. East Hanover, NJ: Millicent U.S. Inc.; November 2020.
3. Osphena [package insert]. Princeton, NJ: Duchesnay USA, Inc.; February 2024..
4. Premarin cream [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals LLC; February 2024.
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.
6/2024	Annual review. Updated references.