Clinical Policy: Prasterone (Intrarosa)

Reference Number: PA.CP.PMN.99
Effective Date: 12/2016
Last Review Date: 01/2023

Revision Log

Description
Prasterone (Intrarosa®) is an inactive endogenous steroid and is converted into active androgens and/or estrogens.

FDA Approved Indication(s)
Intrarosa is indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness that Intrarosa is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Dyspareunia (must meet all)**:**

1. Diagnosis of dyspareunia due to menopause;
2. Age ≥ 18 years;
3. Failure of two vaginal lubricants or vaginal moisturizers, unless clinically significant adverse effects are experienced or all are contraindicated (*see Appendix B*);
4. Failure of ≥ 4 week trial of one vaginal estrogen (e.g., estradiol vaginal cream (Estrace®), estradiol vaginal insert (Vagifem®), Premarin® vaginal cream), unless clinically significant adverse effects are experienced or all are contraindicated (*see Appendix B*);
5. Dose does not exceed one vaginal insert daily.

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to PA.CP.PMN.53.

II. Continued Therapy

A. Dyspareunia (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy (e.g., dyspareunia symptom reduction);
3. If request is for a dose increase, new dose does not exceed one vaginal insert daily.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to PA.CP.PMN.53.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – PA.CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug	Dosing Regimen	Dose Limit/ Maximum Dose
estradiol vaginal cream (Estrace®)	Initial: 2 to 4 gm vaginally QD for 1 to 2 weeks, gradually reduce to 50% of initial dose for 1 to 2 weeks Maintenance: 1 gm 1 to 3 times a week	Varies
Premarin® (conjugated estrogens) vaginal cream	0.5 gm intravaginally twice per week continuously	Varies
estradiol vaginal insert (Vagifem®)	1 insert intravaginally daily for 2 weeks, followed by 1 insert twice weekly	1 insert/day
Vaginal Lubricants: *Water-based* Astroglide, FemGlide, Just Like Me, K-Y Jelly, Pre-Seed, Slippery Stuff, Summer's Eve *Silicone-based* ID Millennium, Pink, Pjur, Pure Pleasure	Apply intravaginally before sex	Varies
Vaginal moisturizers: Fresh Start, K-Y Silk-E, Moist Again, Replens, K-Y Liquibeads	Apply intravaginally before sex	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): undiagnosed abnormal genital bleeding
- Boxed warning(s): none reported

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Dyspareunia due to menopause	Administer one vaginal insert once daily at bedtime, using the provided applicator	1 insert/day

VI. Product Availability

Vaginal insert: 6.5 mg

VII. References

1. Intrarosa Prescribing Information. Quebec City, Canada: Endoceutics Inc., November 2020. Available at: http://us.intrarosa.com/. AccessedOctober 10, 2022.
2. American College of Obstetricians and Gynecologists Committee on Practice Bulletins-Gynecology. ACOG Practice Bulletin No. 213: Female sexual dysfunction. Obstet Gynecol. 2019;134(1):e1-e18.
3. Management of symptomatic vulvovaginal atrophy: 2013 position statement of The North American Menopause Society. Menopause. 2013;20:888-902.
4. Clinical Care Recommendations, Chapter 3: Clinical Issues. The North American Menopause Society. Available at: http://www.menopause.org/publications/clinical-care-recommendations/chapter-3-clinical-issues. Accessed October 10, 2022.
5. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed October 10, 2022.
6. North American Menopause Society (NAMS) Position Statement: The 2020 genitourinary syndrome of menopause position statement of The NAMS. *Menopause: The Journal of The North American Menopause Society*. 2020: 27(9); 976-92.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2019 annual review: references reviewed and updated.	01/2019	
1Q 2020 annual review: references reviewed and updated.	01/2020	
1Q 2021 annual review: no significant changes; references reviewed and updated.	01/2021	
1Q 2022 annual review: no significant changes; references reviewed and updated.	01/2022	
1Q 2023 annual review: no significant changes; references reviewed and updated.	01/2023	