Clinical Policy: Prasterone (Intrarosa)

Reference Number: ERX.NPA.02
Effective Date: 04.01.17
Last Review Date: 02.22
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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 (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 contraindicated or clinically significant adverse effects are experienced (*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 contraindicated or clinically significant adverse effects are experienced (*see Appendix B*);
5. Dose does not exceed one vaginal insert daily.

Approval duration:
Medicaid – 12 months
Commercial – Length of Benefit

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
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:
Medicaid – 12 months
Commercial – Length of Benefit

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym 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 and may require prior authorization.

Drug Name	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

Indication	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/. Accessed November 11, 2021.
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 November 11, 2021.
5. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed November 11, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q18 annual review: Added age limit. Added specific formulary alternative vaginal estrogens. Added example of what constitutes a response to therapy for reauthorization.	11.22.17	02.18
1Q 2020 annual review: no significant changes; added Medicaid line of business with 12 month approval durations; references reviewed and updated.	11.04.19	02.20
1Q 2021 annual review: no significant changes; references reviewed and updated.	10.22.20	02.21
1Q 2022 annual review: no significant changes; added Appendix C; references reviewed and updated.	11.11.21	02.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.