Clinical Policy: Prasterone (Intrarosa)

Reference Number: PA.CP.PMN.99
Effective Date: 12.20.16 Revision Log
Last Review Date: 07.18

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 health plans affiliated with 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 (at up to maximally indicated doses), unless contraindicated or clinically significant adverse effects are experienced;
4. Failure of one vaginal estrogen at up to maximally indicated doses (e.g., Estrace vaginal cream, Premarin vaginal cream, Vagifem vaginal insert) for at least 4 weeks, unless contraindicated or clinically significant adverse effects are experienced;
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;
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.
   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
Not applicable

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
Estrace® (estradiol) vaginal cream	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
Vagifem® (estradiol) vaginal insert	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

Drug	Dosing Regimen	Dose Limit/Maximum Dose
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.

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	One vaginal insert daily

VI. Product Availability

Supplied vaginal inserts (containing 6.5 mg of prasterone) boxes of 4 blister packs containing 7 vaginal inserts (28 vaginal inserts per box)

VII. References

1. Intrarosa Prescribing Information. Quebec City, Canada: Endoceutics Inc., April 2017. Available at: http://us.intrarosa.com/. Accessed November 22, 2017.
2. American College of Obstetricians and Gynecologists Committee on Practice Bulletins-Gynecology. ACOG Practice Bulletin No. 119: Female sexual dysfunction. Obstet Gynecol. 2011;117:996-1007.
3. Management of symptomatic vulvovaginal atrophy: 2013 position statement of The North American Menopause Society. Menopause. 2013;20:888-902.
4. Vaginal and Vulvar Comfort: Lubricants, Moisturizers, and Low-dose Vaginal Estrogen. The North American Menopause Society. Available at: https://www.menopause.org/for-women/sexual-health-menopause-online/effective-treatments-for-sexual-problems/vaginal-and-vulvar-comfort-lubricants-moisturizers-and-low-dose-vaginal-estrogen. Accessed November 22, 2017.
5. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed November 22, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date