


Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	Submission Date: 02/01/2025
Policy Number: PA.CP.PMN.99	Effective Date: 01/2018 Revision Date: 01/2025
Policy Name: Prasterone (Intrarosa)	
<p>Type of Submission – <u>Check all that apply:</u></p> <ul style="list-style-type: none"> <input type="checkbox"/> New Policy <input checked="" type="checkbox"/> Revised Policy* <input type="checkbox"/> Annual Review - No Revisions <input type="checkbox"/> Statewide PDL - <i>Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.</i> 	
<p>*All revisions to the policy <u>must</u> be highlighted using track changes throughout the document.</p> <p>Please provide any changes or clarifying information for the policy below:</p> <p>1Q 2025 annual review: no significant changes; references reviewed and updated.</p>	
Name of Authorized Individual (Please type or print): Craig A. Butler, MD MBA	Signature of Authorized Individual: 

Clinical Policy: Prasterone (Intrarosa)

Reference Number: PA.CP.PMN.99

Effective Date: 12/2016

Last Review Date: 01/2025

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 \geq 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 \geq 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.PHARM.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.PHARM.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 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: <u>Water-based</u> Astroglide, FemGlide, Just Like Me, K-Y Jelly, Pre-Seed, Slippery Stuff, Summer's Eve <u>Silicone-based</u> 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: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ada639d4-bac0-2ad0-e053-2a95a90afce7>. Accessed October 22, 2024.
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. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed October 10, 2022.
5. 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.
6. Christmas M, Huguenin A, Iyer S. Clinical Practice Guidelines for Managing Genitourinary Symptoms Associated With Menopause. *Clin Obstet Gynecol.* 2024 Mar 1;67(1):101-114.

Reviews, Revisions, and Approvals	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
1Q 2024 annual review: no significant changes; references reviewed and updated.	01/2024

Reviews, Revisions, and Approvals	Date
1Q 2025 annual review: no significant changes; references reviewed and updated.	01/2025