# Clinical Policy: Prasterone (Intrarosa)

Reference Number: CP.PMN.99
Effective Date: 12.20.16
Last Review Date: 02.22
Line of Business: Commercial, HIM, 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.*

It is the policy of health plans affiliated with Centene Corporation® 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/HIM** – 12 months
**Commercial** – 12 months or duration of request, whichever is less

**B. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

## II. Continued Therapy

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

1. Currently receiving medication via Centene 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:**
**Medicaid/HIM** – 12 months
**Commercial** – 12 months or duration of request, whichever is less

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   **Approval duration: Duration of request or 12 months (whichever is less)**; or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

## 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 – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid 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<br>Maintenance: 1 gm 1 to 3 times a week | Varies |
| Premarin® (conjugated estrogens) vaginal cream | 0.5 gm intravaginally twice per week continuously | Varies |

| Drug | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| estradiol vaginal insert (Vagifem®) | 1 insert intravaginally daily for 2 weeks, followed by 1 insert twice weekly | 1 insert/day |
| Vaginal Lubricants:<br>*Water-based* Astroglide, FemGlide, Just Like Me, K-Y Jelly, Pre-Seed, Slippery Stuff, Summer's Eve<br>*Silicone-based* ID Millennium, Pink, Pjur, Pure Pleasure | Apply intravaginally before sex | Varies |
| Vaginal moisturizers:<br>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/. 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:<br>- Policies combined for Centene Commercial and Medicaid lines of business<br>- No significant changes<br>- Added age limit<br>- Added specific formulary alternative vaginal estrogens.<br>- Added example of what constitutes a response to therapy for reauthorization<br>- References reviewed and updated. | 11.22.17 | 02.18 |
| 1Q 2019 annual review: no significant changes; references reviewed and updated. | 11.01.18 | 02.19 |
| 1Q 2020 annual review: no significant changes; references reviewed and updated. | 11.04.19 | 02.20 |
| 1Q 2021 annual review: HIM line of business added; no significant changes; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated. | 10.22.20 | 02.21 |
| 1Q 2022 annual review: no significant changes; revised Commercial approval duration from "Length of Benefit" to "12 months or duration of request, whichever is less"; 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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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**Note:**
**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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