MEDICAL MUTUAL®

Drug Policy

Policy:	Intrarosa (prasterone)	Annual Review Date: 03/21/2024 Last Revised Date: 03/21/2024

OVERVIEW

Intrarosa is a steroid for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause.

POLICY STATEMENT

This policy involves the use of Intrarosa. Prior authorization is recommended for pharmacy benefit coverage of Intrarosa. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Intrarosa is recommended in those who meet the following criteria:

1. **Moderate to Severe Dyspareunia**
   Criteria. *Patient must meet the following criteria*
   - **A.** The patient is a post-menopausal woman with a diagnosis of moderate-to-severe dyspareunia due to vulvar and vaginal atrophy; AND
   - **B.** The patient meets one of the following:
     - **a.** The patient has tried and failed a low dose estrogen preparation (e.g. generic estradiol vaginal cream, generic estradiol vaginal insert, Yuvafem, Premarin vaginal cream, Estrace vaginal cream, Estring, Vagifem); OR
     - **b.** According to the prescriber, the patient is at an increased risk of endometrial cancer, stroke, and/or deep vein thrombosis (DVT); AND
   - **C.** The patient does not have any of the following contraindications to Intrarosa:
     - **a.** Undiagnosed abnormal genital bleeding
     - **b.** Pregnant or breastfeeding
     - **c.** Current or past history of breast cancer; AND
   - **D.** The patient does not have renal or hepatic impairment; AND

E. Use of Intrarosa will be for the shortest duration consistent with treatment goals and risks for the individual woman. Postmenopausal women should be re-evaluated periodically as clinically appropriate to determine if treatment is still necessary

2. Moderate to Severe Dyspareunia, Continuation of Therapy
Criteria. *Patient must meet the following criteria*

A. The patient meets all of the criteria for new starts above; AND
B. Patient has been evaluated and seen improvement on Intrarosa, as determined by the prescriber

Initial Approval/ Extended Approval.
A) *Initial Approval:* 3 months (90 days)
B) *Extended Approval:* 1 year (365 days)

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Intrarosa has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Intrarosa [package insert]. Endocetuics Inc., Quebec City, Canada. November 2021.
2. Prasterone. In: DRUGDEX [online database]. Truven Health Analytics. Greenwood Village, CO. Last updated 12 August 2023. Accessed on 18 March 2024.