

Intrarosa (prasterone) Effective January 1, 2020 ☐ MassHealth UPPL Plan Prior Authorization □ Commercial/Exchange **Program Type** ☐ Quantity Limit □ Pharmacy Benefit Benefit ☐ Step Therapy ☐ Medical Benefit Specialty N/A Limitations **Medical and Specialty Medications** All Plans Phone: 877-519-1908 Fax: 855-540-3693 Contact Information **Non-Specialty Medications All Plans** Phone: 800-711-4555 Fax: 844-403-1029 **Exceptions** N/A

Overview

Intrarosa is a vaginal insert of a synthetic steroid FDA indicated for the treatment of moderate to severe dyspareunia (a symptom of vulvar and vaginal atrophy due to menopause).

Coverage Guidelines

Authorization may be granted for members who are currently receiving treatment with Intrasosa, excluding when the product is obtained as samples or via manufacturer's patient assistance program

OR

Authorization may be granted when all of the following criteria are met, and documentation has been provided:

- 1. The member is a post-menopausal woman with a diagnosis of moderate to severe dyspareunia due to vulvar and vaginal atrophy
- 2. The member tried and failed therapy with or the provider indicates clinical inappropriateness of treatment with at least two alternative agents (e.g. Premarin vaginal cream, Estrace vaginal cream, Estring, Vagifem)

Limitations

- 1. Initial approvals will be granted 3 months
- 2. Reauthorizations will be granted for 12 months when a physician assessment of improvement in the member's condition has been submitted.
- 3. The following quantity limits apply:

Intrarosa	1 box (28 inserts) per 28 days

References

- 1. Intrarosa (prasterone) [prescribing information]. Quebec City, Canada: Endoceutics; February 2018
- 2. Management of symptomatic vulvovaginal atrophy: 2013 position statement of The North American Menopause Society. Menopause 2013; 20:888

- 3. Martel C, Labrie F, Archer DF, et al. Serum steroid concentrations remain within normal postmenopausal values in women receiving daily 6.5mg intravaginal prasterone for 12 weeks. J Steroid Biochem Mol Biol 2016; 159:142
- 4. Labrie F, Derogatis L, Archer DF, et al. Effect of Intravaginal Prasterone on Sexual Dysfunction in Postmenopausal Women with Vulvovaginal Atrophy. J Sex Med 2015; 12:2401
- 5. Santen RJ, Mirkin S, Bernick B, Constantine GD. Systemic estradiol levels with low-dose vaginal estrogens. Menopause 2020; 27:361
- 6. Constantine G, Millheiser LS, Kaunitz AM, et al. Early onset of action with a 17β-estradiol, softgel, vaginal insert for treating vulvar and vaginal atrophy and moderate to severe dyspareunia. Menopause 2019

Review History

11/20/19 – Reviewed at P&T 11/18/2020- Reviewed at P&T.

