Clinical Policy: Prasterone (Intrarosa)
Reference Number: CP.PMN.99
Effective Date: 12.20.16
Last Review Date: 02.20
Line of Business: Commercial, Medicaid

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;
      4. Failure of ≥ 4 week trial of one vaginal estrogen (e.g., Estrace vaginal cream, Premarin vaginal cream, Vagifem vaginal insert), unless contraindicated or clinically significant adverse effects are experienced;
      5. Dose does not exceed one vaginal insert daily.

   Approval duration:
   Medicaid – 12 months
   Commercial - Length of Benefit

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 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 – 12 months
Commercial - Length of Benefit

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 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 and CP.PMN.53 for Medicaid.

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.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dosing Regimen</th>
<th>Dose Limit/ Maximum Dose</th>
</tr>
</thead>
</table>
| 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:                 | Apply intravaginally before sex                                              | Varies                   |
Prasterone

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Water-based</em> Astroglide, FemGlide, Just Like Me, K-Y Jelly, Pre-Seed, Slippery Stuff, Summer’s Eve <em>Silicone-based</em> ID Millennium, Pink, Pjur, Pure Pleasure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaginal moisturizers: Fresh Start, K-Y Silk-E, Moist Again, Replens, K-Y Liquibeads</td>
<td>Apply intravaginally before sex</td>
<td>Varies</td>
</tr>
</tbody>
</table>

*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

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dyspareunia due to menopause</td>
<td>Administer one vaginal insert once daily at bedtime, using the provided applicator</td>
<td>1 insert/day</td>
</tr>
</tbody>
</table>

VI. Product Availability

Vaginal inserts: 6.5 mg

VII. References


Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Review Type</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
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<tbody>
<tr>
<td>Created new criteria.</td>
<td>12.20.16</td>
<td>02.17</td>
</tr>
<tr>
<td>Added therapeutic alternatives, updated standard language per template.</td>
<td>01.17.17</td>
<td>02.17</td>
</tr>
<tr>
<td>Converted to new template. Minor changes to verbiage and grammar.</td>
<td>07.18.17</td>
<td>11.17</td>
</tr>
<tr>
<td>1Q18 annual review:</td>
<td>11.22.17</td>
<td>02.18</td>
</tr>
</tbody>
</table>
**CLINICAL POLICY**

Prasterone

<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
</table>
| - Policies combined for Centene Commercial and Medicaid lines of business  
- No significant changes  
- Added age limit  
- Added specific formulary alternative vaginal estrogens.  
- Added example of what constitutes a response to therapy for reauthorization  
- References reviewed and updated. | 11.01.18    | 02.19            |
| 1Q 2019 annual review: no significant changes; references reviewed and updated. | 11.04.19    | 02.20            |

**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.

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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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