Program Number | 2021 P 2242-1
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Program | Prior Authorization/Medical Necessity
Medication | Intrarosa (prasterone)
P&T Approval Date | 6/2021
Effective Date | 1/1/2022; Oxford only: 1/1/2022

1. **Background:**
   Imvexxy (estradiol) vaginal insert, Intrarosa (prasterone) vaginal insert, Osphena (ospemifene) oral tablet, and Premarin (conjugated estrogens) vaginal cream are indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy (VVA), due to menopause. Osphena is also indicated for the treatment of moderate to severe vaginal dryness, a symptom of VVA, due to menopause and Premarin vaginal cream is indicated for the treatment of atrophic vaginitis and kraurosis vulvae.

2. **Coverage Criteria**:  

   A. **Initial Authorization**

   1. **Intrarosa** will be approved based on **all** of the following criteria*:

      a. Diagnosis of moderate to severe dyspareunia

      - AND-

      b. Patient has vulvar and vaginal atrophy due to menopause

      -AND-

      c. History of failure, contraindication, or intolerance **two** of the following:

         1) Imvexxy (estradiol)
         2) Osphena (ospemifene)
         3) Premarin vaginal cream

   **Authorization will be issued for 12 months**

   2. **Reauthorization**

   a. **Intrarosa** will be approved based on the following criterion:

      (1) Documentation of positive clinical response to therapy

   **Authorization will be issued for 12 months**

   * State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization
management programs may apply.

3. **Additional Clinical Rules:**
   - Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
   - Supply limits may be in place.

* Coverage of medications for the treatment dyspareunia is based on benefit design. Please refer to member’s specific benefits for coverage determination.

4. **References:**

<table>
<thead>
<tr>
<th>Program</th>
<th>Prior Authorization/Medical Necessity - Intrarosa</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Change Control</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Date</strong></td>
<td><strong>Change</strong></td>
</tr>
<tr>
<td>6/2021</td>
<td>New program</td>
</tr>
</tbody>
</table>