SmartPA Criteria

Drug/Drug Class: Orilissa™ (elagolix) Clinical Edit
First Implementation Date: July 24, 2019
Prepared for: MO HealthNet
Prepared by: MO HealthNet/Conduent
Criteria Status: ☒ New Criteria

Executive Summary

Purpose: Ensure appropriate utilization of Orilissa™ (elagolix) oral tablets.

Why was this Issue Selected: Orilissa™ is an oral gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for management of moderate to severe pain associated with endometriosis in women 18 years of age and older. Orilissa™ inhibits endogenous GnRH signaling by binding to GnRH receptors in the pituitary gland resulting in dose-dependent suppression of luteinizing hormone and follicle-stimulating hormone. Subsequent suppression of estradiol levels then occurs. Endometriosis is a chronic disease that affects about 6% to 10% of women in the United States. Current treatment includes both pharmacological and surgical options. Some of the pharmacological options include NSAIDS, extended-cycle combined oral contraceptives, progestin therapy, and GnRH agonists.

Program-specific information:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Cost per Claim</th>
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</thead>
<tbody>
<tr>
<td>Orilissa™</td>
<td>$844.87/mo WAC</td>
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Type of Criteria: ☐ Increased risk of ADE  ☐ Preferred Drug List
☒ Appropriate Indications  ☒ Clinical Edit

Data Sources: ☐ Only administrative databases  ☒ Databases + Prescriber-supplied

Setting & Population

- Drug for review: Orilissa™ (elagolix)
- Age range: all appropriate MO HealthNet participants aged 18 years or older

Approval Criteria

- Participant is 18 years of age or older
- Documented diagnosis of moderate to severe pain associated with endometriosis
• Documented trial of alternative therapy:
  o NSAIDS - trial defined as 30/180 days **AND**
  o Combined contraceptive therapy – trial defined as 180/270 days – **OR**
  o Progesterone/Progestin therapy:
    ▪ Injectable contraceptive trial defined as 2 claims in 270 days **OR**
    ▪ Medroxyprogesterone tablets trial defined as 30/90 days **OR**
    ▪ Norethindrone acetate trial defined as 180/270 days
• For 200mg tablets only:
  o Participant has documented diagnosis of dyspareunia
• Max allowable quantity and duration:
  o Moderate hepatic impairment (Child-Pugh B): 150mg/day for up to 6 months
  o Mild to no hepatic impairment (Child-Pugh A): 150mg/day for up to 24 months

**Denial Criteria**

• Therapy will be denied if no approval criteria are met
• Participant is pregnant
• Participant has documented diagnosis of osteoporosis
• Participant has documented diagnosis of severe hepatic impairment (Child-Pugh C)
• For 200mg tablets only:
  o Documented diagnosis of moderate hepatic impairment (Child-Pugh B)

**References**

2) Orilissa product information
3) 1998-2018 Mayo Foundation for Medical Education and Research (MFMER).