Orilissa (elagolix)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Initial Requests: 6 months Continued Therapy Requests: 6 months Total approval duration should not exceed 24 months (2 years).

Medications	Quantity Limit
Orilissa (elagolix)	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Orilissa (elagolix) may be approved if the following criteria are met:

I. Individual is female age 18 or over; **AND**
II. Individual has moderate or severe endometriosis-associated pain;

AND

III. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to both of the following agents or has a contraindication (ACOG 2010):
   A. Nonsteroidal anti-inflammatory drugs (NSAIDs); **AND**
   B. Hormonal contraceptives;
   OR
   C. Progestins (oral or depot (e.g. norethindrone, medroxyprogesterone));

AND

IV. Individual has not previously received an elagolix-containing product (Orilissa or Oriahnn); **OR**
V. Individual has utilized elagolix-containing products (Orilissa, Oriahnn) for a combined total duration of less than 24 months in their lifetime; **OR**
VI. Individual is using high dose (200 mg twice daily) or has moderate hepatic impairment (Child-Pugh class B),and has utilized Orilissa (elagolix) for a combined total duration of less than 6 months in their lifetime.

Continuation requests for Orilissa (elagolix) may be approved if the following criteria are met:

I. Individual has experienced a clinically significant improvement in endometriosis-associated pain; **AND**
II. One of the following:
   A. Individual has utilized elagolix-containing products (Orilissa, Oriahnn) for a combined total duration of less than 24 months in their lifetime; **OR**

B. Individual has moderate (Child-Pugh Class B) hepatic impairment and has used Orilissa for a combined total duration of less than 6 months during lifetime; **OR**
C. Individual has utilized Orilissa (elagolix) 200 mg for a combined total duration of less than 6 months during lifetime.

Requests for Orilissa (elagolix) may **not** be approved for the following:

I. Individual has osteoporosis; **OR**
II. Individual has severe hepatic impairment (Child-Pugh class C); **OR**
III. Individual is requesting in combination with hormonal contraceptives; **OR**
IV. Individual is requesting in combination with contraindicated agents, including, but not limited to, strong OATP1B1 inhibitors (for example: cyclosporine or gemfibrozil); OR
V. Individual has used elagolix-containing products (Orilissa, Oriahnn) for a combined total of 24 months or more per lifetime.

Key References:

1. American College of Obstetricians and Gynecologists. ACOG Practice Bulletin 114. Management of endometriosis. *Obstet Gynecol.* 2010;116:223-36.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: May 11, 2022.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
6. Orilissa (elagolix) tablets for oral use [Package Insert]. North Chicago, IL: AbbVie Inc; February 2021.
7. Schrager S, Falleroni J, Edgoose J. Evaluation and Treatment of Endometriosis. *Am Fam Physician*. 2013; 87(2):107-113.
8. Taylor HS, Giudice LC, Lessey BA et al. Treatment of endometriosis-associated pain with elagolix, an oral GnRH antagonist. *New Engl J Med.* 2017; 377:28-40.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.