

## Orilissa Drug Use Criteria

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Includes:

**Orilissa®** (*Elagolix*)

### GUIDELINE FOR USE:

#### Initial Request:

1. Is this request for management of moderate to severe pain associated with endometriosis in a woman >18 years of age?
  - a. If yes, go to 2
  - b. If no, deny as not meeting criteria. The requested product is not FDA-approved for the indicated diagnosis. Off-label use of a medication is not a covered benefit on OHP.
2. Has the member tried and failed an adequate trial of at least 1 of the preferred first line endometriosis therapy options for at least 3 months including administration of combined hormonal contraceptives or progestins (oral, depot injection, or intrauterine) alone? OR Does the patient have a documented intolerance, FDA-labeled contraindication, or hypersensitivity the first-line therapy options?
  - a. If yes, go to 3
  - b. If no, deny as not meeting criteria. Trial with at least one first line therapy option such as hormonal contraceptives or progestins is required for at least 3 months.
3. Has member tried and failed an adequate trial of at least 1 of the preferred second line endometriosis therapy options for at least 3 months, including Synarel (nafarelin) or Lupron Depot (leuprolide)?
  - a. If yes, go to 4
  - b. If no, deny as not meeting criteria. Trial with at least one second line therapy option (Synarel or Lupron Depot) is required for at least 3 months. (PA required)
4. Has member previously received treatment with:
  - greater than or equal to 24 cumulative months with: Orilissa 150mg once daily, Oriahnn, or Myfembree, OR
  - Greater than or equal to 6 cumulative months with: Orilissa 200mg twice daily
  - a. If no, go to 5
  - b. If yes, deny as not meeting criteria. Maximum recommended treatment course exceeded.
5. Does member have normal liver function or mild hepatic impairment (Child-Pugh Class A) as supported by provided LFT lab data?
  - a. If yes, approve Orilissa 150mg daily for up to 12 months OR Orilissa 200mg twice daily for up to 6 months
  - b. If no, go to 6

6. Does member have moderate hepatic impairment (Child-Pugh Class B) as supported by provided LFT lab data?
  - a. If yes, approve Orilissa 150mg daily for up to 6 months ONLY. [Orilissa 200mg twice daily is not recommended with current level of hepatic impairment]
  - b. If no, deny as not meeting criteria. Treatment with Orilissa is not recommended with current level of hepatic impairment.

**Renewal Request:**

1. Has member received any ONE of the following regimens?
  - A 6-month course of Orilissa 200mg twice daily
  - A 6-month course of Orilissa 150mg once daily and the member has moderate hepatic impairment (Child-Pugh Class B)
  - A 24-month course of Orilissa 150mg once daily and the member has normal liver function or mild hepatic impairment (Child-Pugh Class A)
  - a. If yes, deny as not meeting criteria. Member has reached the maximum recommended treatment course for this medication.
  - b. If no, go to 2
2. Has member had improvement of pain related to endometriosis while on therapy?
  - a. If yes, go to 3
  - b. If no, deny as not meeting criteria. Recommend changing treatment plan to optimize member response.
3. Does member have normal liver function or mild hepatic impairment (Child-Pugh Class A)?
  - a. If yes, approve up to the following maximum cumulative doses:
    - i. Orilissa 150mg daily up to cumulative treatment of 24 months (including previous fills)
    - ii. Orilissa 200mg twice daily up to cumulative treatment of 6 months (including previous fills).
  - b. If no, deny as not meeting criteria. Treatment with Orilissa is not recommended for patients with moderate or severe hepatic impairment (Child-Pugh Class B or Class C).

**Rationale:**

To promote cost-effective treatment of covered OHP conditions.

**FDA Approved Indications:**

Orilissa (Elagolix) is indicated for the management of moderate to severe pain associated with endometriosis.

**Mechanism of Action:**

Elagolix is a short-acting, nonpeptide, gonadotropin-releasing hormone antagonist that suppresses pituitary and ovarian hormone function in a dose-dependent manner. Concentrations of LH, FSH, and estradiol are decreased

during therapy and rapidly return to previous levels once treatment is discontinued. In patients with endometriosis, these actions reduce dysmenorrhea and nonmenstrual pelvic pain.

**Dosing:**

Adults:

- 150 mg once daily for a maximum duration of 24 months
- May increase to 200 mg twice daily for severe symptoms (eg, dyspareunia), for a maximum duration of 6 months.

**Contraindications:**

- Hypersensitivity to elagolix or any component of the formulation;
- Pregnancy
- known osteoporosis
- severe hepatic impairment (Child-Turcotte-Pugh class C)
- concomitant use of organic anion transporting polypeptide (OATP) 1B1 that are known or expected to significantly increase elagolix plasma concentrations

**References:**

1. Lupaneta Pack [package insert]. North Chicago, IL: AbbVie Inc.; June 2015.
2. Lupron Depot [package insert]. North Chicago, IL: AbbVie Inc.; October 2023.
3. Myfembree [package insert]. Brisbane, CA: Myovant Sciences, Inc.; August 2023.
4. Oriahnn [package insert]. North Chicago, IL: AbbVie Inc.; June 2023.
5. Orilissa [package insert]. North Chicago, IL: AbbVie Inc.; June 2023.
6. Synarel [package insert]. New York, NY: Pfizer Inc.; January 2023.
7. Zoladex 3.6 mg [package insert]. Deerfield, IL: TerSera Therapeutics LLC; March 2023.
8. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023.
9. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA.
10. Schrager S, Falleroni J, Edgoose J. Evaluation and treatment of endometriosis. *Am Fam Physician*. 2013;87(2):107-13.
11. Management of endometriosis. Practice Bulletin No. 114. American College of Obstetricians and Gynecologists. *Obstet Gynecol*. 2010;116:223-236.
12. Edi R, Cheng T. Endometriosis: Evaluation and Treatment. *Am Fam Physician*. 2022;106(4):397-404.