AdvancedHealth
Bridging the Future of Healthcare

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Orilissa Drug Use Criteria

Created: October 2024
Reviewed: February 2025

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

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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

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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:

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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.