PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Orilissa (elagolix)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Orilissa is a gonadotropin-releasing hormone (GnRH) receptor antagonist initially approved by the FDA in 2018. It is indicated for the management of moderate to severe pain associated with endometriosis. Orilissa causes a dose-dependent decrease in bone mineral density (BMD), which is greater with increasing duration of use and may not be completely reversible after stopping treatment. Therefore, treatment should be limited to no more than 24 months to reduce the extent of bone loss.

Orilissa (elagolix) will be considered for coverage when the following criteria are met:

Endometriosis

For **initial** authorization:

1. Member is premenopausal and 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a gynecologist; AND
3. Member has a diagnosis of endometriosis confirmed by imaging or laparoscopy; AND
4. Member must have documentation of painful symptoms (e.g., pelvic pain, dysmenorrhea, etc.) associated with endometriosis; AND
5. Member has failed a 3-month trial of a hormonal contraceptive; AND
6. Provider attests that member does **NOT** have **ANY** of the following:
   a) Pregnancy or plan to become pregnant while taking medication;
   b) Current or history of thrombotic or thromboembolic disorders;
   c) High risk of thrombotic or thromboembolic disorder (e.g., uncontrolled hypertension, smoker over 35 years of age, etc.);
   d) Current use of a strong OATP1B1 inhibitor (e.g., cyclosporine, gemfibrozil, etc.).
7. **Dosage allowed/Quantity limit:** Administer 150 mg orally once daily for 24 months. If coexisting dyspareunia is present, administer 200 mg orally twice daily for 6 months.

If member meets all the requirements listed above, the medication will be approved for 24 months when the dose requested is 150 mg and for 6 months when the dose requested is 200 mg.

For **reauthorization**:

1. Orilissa will not be reauthorized.

CareSource considers Orilissa (elagolix) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
11/20/2018	New policy for Orilissa created.
10/23/2020	Removed requirement of negative pregnancy test or sterilization of partner (changed to no current pregnancy or plan to become pregnant); removed obstetrician as an option for prescriber.
08/23/2022	Annual review. Transferred to new template. Updated references.
03/26/2024	Updated references; added confirmation by imaging or laparoscopy of endometriosis diagnosis; removed 30-day trial of NSAID; removed osteoporosis and severe liver impairment contraindication; added current or history of thrombotic or thromboembolic disorders; removed liver impairment specific dosing and added caveat that 200 mg dose is for coexisting dyspareunia.

References:

1. Orilissa [package insert]. North Chicago, IL: AbbVie Inc.; 2023.
2. Taylor HS, Giudice LC, Lessey BA, et al. Treatment of Endometriosis-Associated Pain with Elagolix, an Oral GnRH Antagonist. *N Engl J Med.* 2017;377(1):28-40. doi:10.1056/NEJMoa1700089
3. Schrager S, Falleroni J, Edgoose J. Evaluation and treatment of endometriosis. *Am Fam Physician.* 2013 Jan 15;87(2):107-13.
4. Armstrong C. ACOG updates guideline on diagnosis and treatment of endometriosis. *Am Fam Physician.* 2011 Jan 1;83(1):84-85.
5. Falcone T, Flyckt R. Clinical Management of Endometriosis. *Obstet Gynecol.* 2018;131(3):557-571. doi:10.1097/AOG.0000000000002469
6. Becker CM, Bokor A, Heikinheimo O, et al. ESHRE guideline: endometriosis. *Hum Reprod Open.* 2022;2022(2):hoac009. Published 2022 Feb 26. doi:10.1093/hropen/hoac009

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