PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Orilissa (elagolix)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
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 is having moderate to severe painful symptoms (e.g., pelvic pain, dysmenorrhea, etc.) associated with endometriosis (documentation required); AND
4. Member has tried and failed to control symptoms after trials with both of the following, unless not tolerated or contraindicated:
   a) 30 days of an NSAID;
   b) 3 months of a hormonal contraceptive; AND
5. Member does not have ANY of the following:
   a) Pregnancy or plan to become pregnant during treatment;
   b) Osteoporosis;
   c) Severe hepatic impairment;
   d) Currently using strong OATP1B1 inhibitors (e.g., cyclosporine, gemfibrozil, etc.)
6. **Dosage allowed/Quantity limit:** 150 mg once daily for 24 months or 200 mg twice daily for 6 months. 150 mg once daily for 6 months for members with moderate hepatic impairment (Child-Pugh Class B).

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

For **reauthorization**:
Orilissa will not be reauthorized for continued therapy.

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.

References:

1. Orilissa [package insert]. North Chicago, IL: AbbVie Inc.; February 2021.
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;377:28-40
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. Obstetrics & Gynecology. 2018; 131(3):557-571.
6. Becker CM, Bokor A, et al. ESHRE guideline: Endometriosis. Human Reproduction Open. Feb 2022; 2022(2): hoac009.

Effective date: 01/01/2023
Revised date: 08/23/2022