CareSource

PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Orilissa (elagolix)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) Alternative preferred product includes Lupron QUANTITY LIMIT— up to 200 mg twice daily
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Orilissa (elagolix) is a **preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

ENDOMETRIOSIS

For **initial** authorization:

1. Member is premenopausal and 18 years of age or older; AND
2. Member is having painful symptoms (e.g., pelvic pain, dysmenorrhea, etc.) associated with endometriosis (documentation required); AND
3. 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
4. Member does **not** have any of the following:
   a) Pregnancy or plan to become pregnant while taking medication;
   b) Osteoporosis;
   c) Severe hepatic impairment;
   d) Currently using strong OATP1B1 inhibitors (e.g., cyclosporine, gemfibrozil, etc.).
5. **Dosage allowed:** 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 the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
11/20/2018	New policy for Orilissa (elagolix) 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.
11/18/2021	Removed specialist requirement

References:

1. Orilissa [package insert]. North Chicago, IL: AbbVie Inc.; August 2019.
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. ClinicalTrials.gov Identifier: NCT01620528. A Clinical Study to Evaluate the Safety and Efficacy of Elagolix in Subjects With Moderate to Severe Endometriosis-Associated Pain. Available at: https://clinicaltrials.gov/ct2/show/NCT01620528. Accessed on July 30, 2018.
4. ClinicalTrials.gov Identifier: NCT01931670. A Global Phase 3 Study to Evaluate the Safety and Efficacy of Elagolix in Subjects With Moderate to Severe Endometriosis-Associated Pain. Available at: https://clinicaltrials.gov/ct2/show/NCT01931670. Accessed on July30, 2018.

Effective date: 01/01/2022
Revised date: 11/18/2021