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 a premenopausal women of 18 years of age or older; AND
2. Member is not currently breast feeding, pregnant, or planning to become pregnant while receiving medication (chart notes documentation of member's assessment with no intention to become pregnant AND negative pregnancy test or evidence of sterilization (partner's sterilization is also acceptable) required with prior authorization request); AND
3. Member does **not** have ANY of the following:
   a) Osteoporosis;
   b) Severe hepatic impairment;
   c) Currently using strong OATP1B1 inhibitors (e.g., cyclosporine and gemfibrozil); AND
4. Medication must be prescribed by gynecologist or obstetrician; AND
5. Endometriosis symptoms, as indicated by one or more of the following:
   a) Dysmenorrhea;
   b) Dyspareunia;
   c) Pelvic pain; AND
6. Member has failed control of symptoms with ALL of the following:
   a) NSAIDs;
   b) Any hormonal contraceptives for at least 3 months or progestin therapy (Depo-Provera, hormonal IUD, progesterone only pill) for at least 3 months.
7. **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**:

1. 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.

References:

1. Orilissa [package insert]. North Chicago, IL: AbbVie Inc.; July 2018.
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: 04/01/2019
Revised date: 11/20/2018