UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Orilissa

Program	Prior Authorization- Orilissa
Medication	Orilissa (elagolix)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	12/2018
Pharmacy and Therapeutics Approval Date	9/2020
Effective Date	11/2020

1. Background:

Orilissa (elagolix) is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the management of moderate to severe pain associated with endometriosis.

2. Coverage Criteria:

A. Orilissa 150 mg

1. Initial Authorization

a. Orilissa 150 mg will be approved based on **all** of the following criteria:

(1) Diagnosis of moderate to severe pain associated with endometriosis

-AND-

(2) Patient is premenopausal

-AND-

(3) History of trial and failure (e.g., inadequate pain relief), contraindication or intolerance after a three month trial of **two** analgesics (e.g., ibuprofen, meloxicam, naproxen)

-AND-

(4) History of trial and failure, contraindication, or intolerance after a three month trial to **one** of the following:

(a) Hormonal contraceptives

(b) Progestins [e.g., norethindrone (generic Aygestin)]

-AND-

(5) Prescribed by or in consultation with **one** of the following:

(a) Obstetrics/Gynecologist (OB/GYN)
(b) Reproductive endocrinologist

Authorization will be issued for 6 months

2. Reauthorization

a. Orilissa 150 mg will be approved based on **all** of the following criteria**:**
(1) Documentation of positive clinical response to therapy
(2) Impact to bone mineral density has been considered
(3) Treatment duration has not exceeded a total of 24 months

Authorization will be issued for 6 months up to a maximum of 24 months
NOTE: Orilissa 150 mg once daily is indicated for a maximum of 24 months.

B. Orilissa 200 mg

1. Initial Authorization

a. Orilissa 200 mg will be approved based on **all** of the following criteria:

(1) Diagnosis of moderate to severe pain associated with endometriosis

-AND-

(2) Patient is premenopausal

-AND-

(3) History of trial and failure (e.g., inadequate pain relief), contraindication or intolerance after a three month trial of **two** analgesics (e.g., ibuprofen, meloxicam, naproxen)

-AND-

(4) History of trial and failure, contraindication, or intolerance after a three month trial to **one** of the following:
(a) Hormonal contraceptives
(b) Progestins [e.g., norethindrone (generic Aygestin)]

-AND-

(5) Prescribed by or in consultation with **one** of the following:
(a) Obstetrics/Gynecologist (OB/GYN)
(b) Reproductive endocrinologist

Authorization will be issued for 6 months

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NOTE: Orilissa 200 mg twice daily is indicated for a maximum of 6 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Orilissa [package insert]. North Chicago, IL: AbbVie Inc.; August 2019.
2. Taylor H, Giudice L, Lessey B, et al. Treatment of endometriosis-associated pain with elagolix, an oral GnRH antagonist. *N Engl J Med* 2017; 377:28-40.
3. The American College of Obstetricians and Gynecologists. Management of endometriosis. Practice Bulletin 114. July 2010 (Reaffirmed 2018). Accessed September 6, 2018.

Program	Prior Authorization– Orilissa
Change Control	
Date	Change
12/2018	New program
10/2019	Annual review. No changes.
9/2020	Annual review. Added Additional Clinical Rules section and updated references.