UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2152-7
Program	Prior Authorization/Medical Necessity
Medication	Orilissa® (elagolix)
P&T Approval Date	10/2018, 10/2019, 9/2020, 9/2021, 9/2022, 2/2023, 2/2024
Effective Date	5/1/2024

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]:

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) Failure after a three-month trial[b] (e.g., inadequate pain relief), contraindication or intolerance of **two** analgesics (e.g., ibuprofen, meloxicam, naproxen)

-AND-

(3) Failure after a three-month trial[b], contraindication, or intolerance to **one** of the following:

(a) Hormonal contraceptives
(b) Progestins [e.g., norethindrone (generic Aygestin®)]

-AND-

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

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

Authorization will be issued for 12 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

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(3) Treatment duration has not exceeded a total of 24 months

Authorization will be issued for 12 months up to a maximum treatment duration of 24 months

NOTE: Orilissa 150 mg once daily is indicated for a maximum treatment duration 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) Failure after a three-month trial[b] (e.g., inadequate pain relief), contraindication or intolerance of **two** analgesics (e.g., ibuprofen, meloxicam, naproxen)

-AND-

(3) Failure after a three-month trial[b], contraindication, or intolerance to **one** of the following:

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

-AND-

(4) 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

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

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.
[b] For Connecticut, Kentucky and Mississippi business, only a 30 day trial will be required.

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)

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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.; June 2023.
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).

Program	Prior Authorization/Medical Necessity – Orilissa
Change Control	
Date	Change
10/2018	New program
10/2019	Annual review. No changes.
9/2020	Annual review. Updated references.
9/2021	Annual review. Updated CT and KY trial language. Updated references.
9/2022	Annual review. Updated mandate language to include Mississippi.
2/2023	Removed the criteria that patient is premenopausal.
2/2024	Annual review. Updated failure language. Updated state mandate language. Updated authorization duration. Updated references.

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