

Commercial/Healthcare Exchange PA Criteria

Effective: November 7th, 2018

Prior Authorization: Orilissa

Products Affected: Orilissa (elagolix) oral tablet

Medication Description:

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

Orilissa binds to gonadotropin-releasing hormone (GnRH) receptors in the pituitary gland and causes a dosedependent suppression of luteinizing hormone (LH) and follicle-stimulating hormone (FSH), ultimately resulting in decreased serum concentrations of estradiol and progesterone.

Covered Uses: For the management of moderate to severe pain associated with endometriosis

Exclusion Criteria:

- 1. Pregnancy
- 2. Osteoporosis
- 3. Severe hepatic impairment (Child Pugh C)

Required Medical Information:

- 1. Diagnosis
- 2. Dose and frequency
- 3. Child Pugh score
- 4. Chart notes documenting the absence of osteoporsosis
- 5. Current and previous medical history (documentation required)

Age Restrictions: 18 years of age or older

Prescriber Restrictions: Prescribed by, or in consultation with, an obstetrics/gynecology or reproductive specialist.

Coverage Duration:

- Initial: 6 months
- Renewal (150 MG): 18 months, maximum of 24 months
- Renewal (200 MG): No renewal

<u>Other Criteria</u>:

Initial:

Approve if the patient meets the following criteria (A, B, C, D, E, AND F):

- A. Patient has a diagnosis of moderate to severe pain associated with endometriosis; AND
- B. Patient is 18 years of age or older; AND
- C. Orilissa is prescribed by, or in consultation with, an obstetrics/gynecology or reproductive specialist; AND
- D. Patient is not pregnant; AND
- E. Patient does not have osteoporsosis; AND
- F. Patient does not have severe hepatic impairment (Child Pugh C).



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Continuation:

Approve if the patient meets the following criteria (A AND B):

- A. Patient continues to meet initial criteria above; AND
- B. Patient is not currently taking 200mg; AND
- C. Patient has not been taking 150mg for greater than 24 months.

<u>References</u>:

1. Orilissa [package insert]. North Chicago, IL; Abbvie. July 2018.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	11/7/2018

