elagolix (Orilissa™)

EOCCO POLICY

Policy Type: PA Pharmacy Coverage Policy: EOCCO021

Description

Elagolix (Orilissa) is an oral gonadotropin-releasing hormone (GnRH) antagonist FDA-approved for pain relating to endometriosis by suppressing estrogen production.

Length of Authorization

- Initial: Three months
- Renewal:
  i. Elagolix (Orilissa) 150 mg: Up to 12 months, maximum total fills should not exceed 24
  ii. Elagolix (Orilissa) 200 mg: Up to three months, maximum total fills should not exceed 6

Quantity limits

Product Name	Dosage Form	Indication	Quantity Limit	DDID
elagolix (Orilissa)	150 mg tablets	Moderate to severe pain associated with endometriosis	30 tablets/30 days	203526 203520
	200 mg tablets		60 tablets/30 days	203527 203521

Initial Evaluation

I. Elagolix (Orilissa) may be considered medically necessary when the following criteria below are met:
   A. The medication is prescribed for treatment of moderate-to-severe pain associated with endometriosis; **AND**
   B. Member does not have history of osteoporosis defined as a T-score less than or equal to -2.5 or Z-score less than -1.5 at the lumbar spine, femoral neck or total hip; **AND**
   C. Member has tried and failed or is contraindicated for the use of oral hormonal contraceptives; **AND**
   D. If continued use of estrogen containing oral contraceptives is planned in combination with Orilissa, the provider acknowledges the efficacy of both the contraceptive and Orilissa may be decreased (use of non-hormonal contraceptives is recommended).

Renewal Evaluation

I. Member has experienced a clinical improvement in pain symptoms relating to endometriosis; **AND**

A. If the request is for elagolix (Orilissa) 150 mg; the member has not received treatment with elagolix (Orilissa) 150 mg for more than 24 months; **OR**
B. If the request is for elagolix (Orilissa) 200 mg**;** the member has not received treatment with elagolix (Orilissa) 200 mg for more than 6 months

Supporting Evidence

I. Elagolix (Orilissa) is an oral GnRH antagonist for the management of moderate to severe pain associated with endometriosis. The drug was studied in two replicate, Phase 3, six-month, multicenter, double-blind, placebo-controlled, randomized controlled trials (Study EM-1 and Study EM-2; Elaris Endometriosis I and II).
   - At three months, both elagolix (Orilissa) 150 mg and 200 mg regimens showed a higher proportion of responders than placebo. Both treatment arms showed statistically significant differences in greater mean decreases in non-menstrual pelvic pain scores from baseline at six months.

II. FDA-approved maximum duration of use for 150 mg tablets is 24 months, though clinical trials studied up to 12 months.

III. FDA approved maximum duration of use for 200 mg tablets is six months. This is the FDA maximum duration of treatment recommended, due to loss of bone marrow density as seen in clinical trials. Bone loss of more than 5% was seen in lumbar spine, total hip and femoral neck with six months of treatment. Studies have not yet been completed to evaluate in combination with bone loss prevention treatments.

IV. For women with mild to moderate pain (e.g. pain symptoms that do not cause regular absence from school or work) and no ultrasound evidence of an endometrioma, first line treatment is nonsteroidal anti-inflammatory drugs (NSAIDs) and continuous hormonal contraceptives because these therapies are low-risk, have few side effects, and provide relief of symptoms for many women. Second-line treatments include GnRH agonists (e.g., leuprolide depot (Lupron), nafarelin acetate (Synarel), goserelin acetate (Zoladex), progestins, and danazol).

V. Clinical trials excluded patients with a Z-score less than -1.5 at the lumbar spine, femoral neck or total hip. Bone loss of more than 5% was seen in lumbar spine, total hip and femoral neck with six months of treatment. Studies have not yet been completed to evaluate in combination with bone loss prevention treatments.

VI. Due to mechanism of action, use of estrogen containing contraceptives are expected to reduce the efficacy of elagolix (Orilissa). Use of elagolix (Orilissa) will reduce efficacy of estrogen containing oral contraceptives. To avoid drug interactions, we recommend provider use of non-hormonal contraceptive during treatment with elagolix (Orilissa).

References

1. Orilissa [Prescribing Information]. North Chicago, IL: AbbVie Inc.; July 2018.
2. UpToDate, Inc. Endometriosis: Treatment of pelvic pain. UpToDate [database online]. Waltham, MA. Updated July 29, 2019.
3. UpToDate, Inc. Clinical manifestations, diagnosis, and evaluation of osteoporosis in postmenopausal women. UpToDate [database online]. Waltham, MA. Updated July 11, 2019.
4. 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. doi: 10.1056/NEJMoa1700089.

Policy Implementation/Update:

Date Created	October 2018
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Last Updated	September 2019
Last Reviewed	10/2018, 09/2019

Action and Summary of Changes	**Date**
Transition from criteria to policy	**09/2019**
Criteria created	10/2018