Oscar Clinical Guideline: Orilissa (elagolix) (PG261, Ver. 2)

Orilissa (elagolix)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Endometriosis is the growth of endometrial-like tissue outside the uterus . The migrated tissues can be found anywhere but are most commonly in the pelvic cavity, usually attached to the reproductive organs. Endometriosis is mainly a disease of the reproductive years, is hormone mediated, and generally associated with menstruation. Symptoms of endometriosis include pelvic pain, painful menstruation, painful intercourse, and subfertility.

Guidelines recommend initial treatment for pain associated with endometriosis of oral contraceptives and/or nonsteroidal anti-inflammatory drugs (NSAIDs). Second-line treatments include GnRH agonists or GnRH antagonists. Observational studies suggest aromatase inhibitors can have improvement for women with chronic pain from endometriosis although evidence is limited.

Orilissa (elagolix) is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the management of moderate to severe pain associated with endometriosis. Dose and duration of use are based on coexisting conditions. It is available as either a 150 mg or 200 mg tablet, and dosing is dependent on hepatic function. Dosing of up to 200 mg twice daily (in those with normal liver function or mild hepatic impairment) has not been studied beyond a total treatment duration of 6 months.

Definitions

"Child-Pugh" refers to a scoring system used to identify those with hepatic impairment and predict mortality in those with cirrhosis (advanced liver disease characterized by permanent scarring on the liver and reduced functionality). Scores range from 5 to 15 with the lowest risk of mortality associated with Child-Pugh classification A (5-6 points), followed by classification B (7-9 points), and the highest risk of mortality associated with Child-Pugh classification C (10-15 points). The Child-Pugh classification is often used to identify those who require medication dosing adjustments for medications that are metabolized at the liver.

"Documentation" refers to written information, including but not limited to:

- Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses; or
- Prescription claims records, and/or prescription receipts to support prior trials of formulary alternatives.

"Dyspareunia," is pelvic pain during or after sexual intercourse.

"Menopause," is marked by natural absence of a woman's menstrual period for 12 months or surgical removal of ovaries and marks the end of their reproductive years.

"No evidence of" indicates that the reviewer has not identified any records of the specified item or condition within the submitted materials or claims history. In the absence of such evidence, the member

is considered eligible. If any evidence of the item or condition is present upon review of the request, the member does not qualify.

"Osteoporosis," is low bone mineral density. Treatment generally is recommended for those with a T-score of negative 2.5 or less.

"[s]" indicates state mandates may apply.

Clinical Indications

Medical Necessity Criteria for Initial Clinical Review

Initial Indication-Specific Criteria

Endometriosis

The Plan considers Orilissa (elagolix) 150 mg or 200 mg medically necessary when ALL of the following criteria are met:

1. The medication is prescribed by or in consultation with a gynecologist or reproductive endocrinologist; *AND*
2. The member is 18 years of age or older; *AND*
3. The member has a diagnosis of endometriosis; *AND*
4. The member is experiencing moderate to severe pain associated with endometriosis; *AND*
5. The member is unable to use, or has tried and failed TWO (2) of the following[s]:
    a. Combined hormonal contraceptive (e.g., levonorgestrel/ ethinyl estradiol, drospirenone/ethinyl estradiol, norgestimate/ethinyl estradiol); *and/or*
    b. Progestogens (e.g., norethindrone) or Progestin contraceptives (e.g., levonorgestrel, norethindrone); *and/or*
    c. Oral nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, meloxicam, naproxen); *AND*
6. The member meets ALL of the following:
    a. No evidence of pregnancy; *and*
    b. No evidence of being in menopause or post-menopausal; *and*
    c. No evidence of known osteoporosis; *and*
    d. No evidence of severe hepatic impairment (Child-Pugh C); *and*
    e. No evidence of organic anion transporting polypeptide (OATP) 1B1 inhibitors that significantly increase Orilissa (elagolix) plasma concentrations (e.g., cyclosporine, gemfibrozil); *AND*
7. Orilissa (elagolix) is being prescribed at a dose and frequency that is within FDA approved labeling OR is supported by compendia or evidence-based published dosing guidelines for the requested indication (see Appendix A).
    The requested medication is being used within the Plan's Quantity Limit of ONE (1) of the following

a. *Orilissa (elagolix) 150 mg once daily: 30 tablets per 30 days*
b. *Orilissa (elagolix) 200 mg twice daily: 60 tablets per 30 days.*

If the above prior authorization criteria are met, the requested product will be authorized for up to 6 months.[5]

- Maximum treatment dose and duration for those with or without dyspareunia and normal liver function or mild hepatic impairment is (see Table 1 Appendix A):
  - Orilissa (elagolix) 200 mg twice daily for up to 6 months.
  - Orilissa (elagolix) 150 mg once daily for up to 24 months.
- Maximum treatment dose and duration for those with moderate hepatic impairment is Orilissa (elagolix) 150 mg once daily for up to 6 months (see Table 1 Appendix A).

Continued Care

Medical Necessity Criteria for Subsequent Clinical Review

Subsequent Indication-Specific Criteria

Endometriosis

The Plan considers Orilissa (elagolix) 150 mg medically necessary when ALL of the following criteria are met:

1. The medication is prescribed by or in consultation with a gynecologist or reproductive endocrinologist; *AND*
2. The member has experienced a documented improvement in pain associated with endometriosis; *AND*
3. The member has normal liver function or mild hepatic impairment; *AND*
4. There is no recorded evidence of unacceptable toxicity to Orilissa (elagolix) (e.g., benefit of treatment outweighs risk of bone loss); *AND*
5. The member meets ALL of the following:
   a. No evidence of pregnancy; *and*
   b. No evidence of being in menopause or post-menopausal; *and*
   c. No evidence of known osteoporosis; *and*
   d. No evidence of organic anion transporting polypeptide (OATP) 1B1 inhibitors that significantly increase Orilissa (elagolix) plasma concentrations (e.g., cyclosporine, gemfibrozil); *AND*
6. Orilissa (elagolix) is being prescribed at a dose and frequency that is within FDA approved labeling OR is supported by compendia or evidence-based published dosing guidelines for the requested indication (see Appendix A).
   The requested medication is being used within the Plan's Quantity Limit of Orilissa (elagolix) 150 mg once daily: 30 tablets per 30 days.

If the above reauthorization criteria are met, the requested product will be authorized for the following:[s]

- Orilissa (elagolix) 150 mg: up to 18 months
    - Maximum treatment duration with Orilissa (elagolix) 150 mg once daily with normal liver function or mild hepatic impairment is 24 months.

Experimental or Investigational or Unproven / Not Medically Necessary[s]

Orilissa (elagolix) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, unproven, or not medically necessary. Non-covered indications include, but are not limited to, the following:

- Pediatric members with endometriosis. The safety and efficacy of Orilissa (elagolix) has not been established in pediatrics.
- Use beyond 24 months for Orilissa (elagolix) 150 mg once daily in those with normal liver function or mild hepatic impairment.
- Use beyond 6 months (at a dose of 150 mg once daily) in those with moderate hepatic impairment.
- Use beyond 6 months for Orilissa (elagolix) at a dose of 200 mg twice daily.

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Appendix A

Table 1: Recommended Dosage and Duration of Use with Orilissa (elagolix)

Dosing Regimen	Maximum Treatment Duration	Coexisting Condition
Initiate treatment with Orilissa (elagolix) 150 mg once daily	24 months	None
Consider initiating treatment with Orilissa (elagolix) 200 mg twice daily	6 months	Dyspareunia

Dosing Regimen	Maximum Treatment Duration	Coexisting Condition
Initiate treatment with Orilissa (elagolix) 150 mg once daily. Use of 200 mg twice daily is not recommended.	6 months	Moderate hepatic impairment (Child-Pugh Class B)

Clinical Guideline Revision / History Information

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