Orilissa (elagolix)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Orilissa is indicated for the management of moderate to severe pain associated with endometriosis.

Orilissa and other GnRH analogues cause a dose-dependent decrease in bone mineral density (BMD). BMD loss is greater with increasing duration of use of Orilissa and other GnRH analogues and may not be completely reversible after stopping treatment. It is recommended to limit the duration of use of Orilissa and other GnRH analogues to reduce the extent of bone loss in patients. The use of higher doses limits use even farther. Therefore, the duration of approval is 24 months for patients taking a maximum of 150 mg once daily, and the duration of approval is 6 months for patients taking 200 mg twice daily.

POLICY

Initial Criteria for Approval

I. Orilissa (elagolix) may be considered **medically necessary** for when the following criteria are met:
   - The patient is 18 years of age or older
   - The patient has the diagnosis of moderate to severe pain associated with endometriosis
   - The patient is not pregnant
   - The patient meets one of the following:
     - Tried and had an inadequate treatment response or intolerance to a 3-month trial of at least one hormonal contraceptive (e.g., combined oral contraceptives, depot medroxyprogesterone, norethindrone acetate, etonogestrel implant, etc.)
     - Has a documented clinical reason such as expected adverse reaction or contraindication that prevents them from trying hormonal contraceptives (e.g., combined oral

contraceptives, depot medroxyprogesterone, norethindrone acetate, etonogestrel implant, etc.)
    - Is currently receiving treatment with the requested product through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) and experiencing a positive therapeutic outcome:
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- The patient does not have osteoporosis or severe hepatic impairment (Child-Pugh Class C)
- The patient is not concomitantly taking an OATP 1B1 inhibitor (i.e. gemfibrozil, cyclosporine, ritonavir, rifampin)
- The patient meets ONE of the following:
    - The request is for 150 mg once daily for a maximum of 24 months and the patient has mild (Child-Pugh class A) or no hepatic impairment
    - The request is for 200 mg twice daily for a maximum of 6 months, the patient has mild (Child-Pugh class A) or no hepatic impairment, and dyspareunia
    - The request is for 150mg once daily for a maximum of 6 months and the patient has moderate hepatic impairment (Child-Pugh class B)

Approval will be for up to **6 months.**

Continuation of Therapy

I. Orilissa (elagolix) may be considered **medically necessary** for the continuation of treatment when the following criteria are met:
- The patient has the diagnosis of moderate to severe pain associated with endometriosis
- The request is for the continuation of 150mg once daily dose
- The patient is not pregnant
- The patient does not have moderate hepatic impairment (Child-Pugh class B)
- The patient is not concomitantly taking an OATP 1B1 inhibitor (i.e. gemfibrozil, cyclosporine, ritonavir, rifampin)
- The patient has experienced a clinically significant improvement in endometriosis-associated pain
- Treatment duration has not exceeded a total of 24 months

Approval will be for up to **18 months.**

Prior approval is required. Submit a prior approval/treatment request now.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

- 200 mg tablets: 56 tablets per 28 days
- 150 mg tablets: 28 tablets per 28 days

Coverage Duration

- 24 months for patients with no coexisting conditions using 150 mg once daily dosing
- 6 months for patients with moderate hepatic impairment (Child-Pugh Class B) using 150 mg once daily dosing
- 6 months for patients with dyspareunia using 200mg twice daily dosing

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- Code(s), if applicable

REFERENCES

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4. Schrager S, Falleroni J, Edgoose J. Evaluation and treatment of endometriosis. Am Fam Physician. 2013 Jan 15;87(2):107-13.
5. Management of endometriosis. Practice Bulletin No. 114. American College of Obstetricians and Gynecologists. Obstet Gynecol 2010;116:223-36.
6. Samy A, Taher A, Sileem SA et al. Medical therapy options for endometriosis related pain, which is better? A systematic review and network meta-analysis of randomized controlled trials. *J Gynecol Obstet Hum Reprod*. 2020;101798. doi: 10.1016/j.jogoh.2020.101798. Online ahead of print.

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POLICY HISTORY

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