

Elagolix (ORLISSA)
Criteria for Use for Endometriosis
March 2024

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National Formulary Committee Monograph on this drug at the [PBM INTRAnet](#) site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive the medication.

- Pregnancy
- Known osteoporosis
- Severe hepatic impairment (Child-Pugh C)
- Concomitant use of organic anion transporting polypeptide (OATP)1B1 (e.g., gemfibrozil, cyclosporine)
- Known hypersensitivity
- Concomitant use of hormonal contraceptives

Inclusion Criteria

All of the following criteria must be met.

- Prescribed by or in consultation with a VA/VA Community Care Gynecology or Women's Health Provider
- Diagnosis of endometriosis (clinical or surgical) in a premenopausal patient
- Contraindication, intolerance, or inadequate response to one alternative treatment (e.g., NSAID, estrogen-containing or progestin-only hormonal contraceptive)
- Assessed for history of suicidal ideation, depression, and mood disorders prior to starting treatment¹
- Planned duration of treatment not to exceed a maximum of 6 months for high dose (200 mg twice daily) or 24 months for low dose (150 mg once daily) elagolix due to risk for bone loss
- Assessed for risk of bone density loss²

Additional Inclusion Criteria

- For patients who can become pregnant: Exclude pregnancy prior to receiving elagolix or start within 7 days of menses onset.
- For patients who can become pregnant: Counseling provided on potential risks vs. benefits of treatment and the use of effective nonhormonal contraception during treatment and for 28 days after stopping treatment.

1. Gonadotropin-releasing hormone receptor antagonists including elagolix have been associated with mood disorders (including depression) and suicidal ideation. Patients should be monitored for mood changes and depressive symptoms after starting treatment.
2. GnRH antagonists including elagolix are associated with bone loss. Per the prescribing information, consider BMD assessment in patients with history of low trauma fracture or risk factors for low bone density.

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