Pharmacy Policy Bulletin

Title: Elagolix sodium (Orilissa™)

Policy #: Rx.01.211

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for **elagolix (Orilissa™)** as provided under the member's prescription drug benefit.

Description:

Endometriosis is defined as endometrial glands and stroma that occur outside the uterine cavity. Lesions are typically in the pelvis; however, they can occur at multiple sites. It affects many women throughout their lifetime and although it is considered nonmalignant, the pain and discomfort associated with the condition can be severe and debilitating.

Elagolix (Orilissa™) is a gonadotropin-releasing hormone (GnRH) receptor antagonist that inhibits endogenous GnRH signaling by binding competitively to GnRH receptors in the pituitary gland. Administration of ORILISSA results in dose-dependent suppression of luteinizing hormone (LH) and follicle-stimulating hormone (FSH), leading to decreased blood concentrations of the ovarian sex hormones, estradiol and progesterone.

Elagolix (Orilissa™) is indicated for the management of moderate to severe pain associated with endometriosis.

Policy:

Elagolix (Orilissa™) is approved when all of the following inclusion criteria are met:

1. Diagnosis of moderate to severe pain associated with endometriosis
2. ONE of the following:
    a. Inadequate response or inability to tolerate BOTH of the following:
        i. One non-steroidal anti-inflammatory drug; and
        ii. Contraceptives; or
    b. Member has had surgical ablation to prevent recurrence

Coverage duration is limited to:

1. 24 months/ lifetime for 150mg tablet

2. 6 months/ lifetime for 200mg tablet

All other treatment durations are considered Experimental/ Investigational.

Black Box Warning as shown in the drug Prescribing Information:

N/A

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Elagolix (Orilissa™) [package insert]. North Chicago, IL. AbbVie, Inc. August 2019. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210450s000lbl.pdf. Accessed July 29, 2020.

Schenken, R. MD Endometriosis: Pathogenesis, clinical features, and diagnosis. UpToDate. Accessed July 29, 2020.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Orilissa™	Elagolix

Cross References:

Off Label Use Rx.01.33

Policy Version Number:	3.00
P&T Approval Date:	July 09, 2020
Policy Effective Date:	October 01, 2020
Next Required Review Date:	July 09, 2021

Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.