



Drug Coverage Policy

Effective Date.....08/01/2024

Coverage Policy Number.....IP0196

Policy Title..... Orilissa

Gonadotropin-Releasing Hormone Antagonists – Orilissa

- Orilissa™ (elagolix tablets – AbbVie)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer’s particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer’s benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer’s benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Cigna Healthcare Coverage Policy

OVERVIEW

Orilissa, an oral gonadotropin-releasing hormone (GnRH) receptor antagonist, is indicated for the management of moderate to severe pain associated with **endometriosis**.¹ Limitation of Use. Limit the duration of use based on the dose and coexisting condition.

The recommended dosage is 150 mg once daily (QD) for up to 24 months (no coexisting conditions) or 200 mg twice daily (BID) for up to 6 months (in patients with coexisting dyspareunia). In patients with moderate hepatic impairment (Child-Pugh Class B), the recommended dosage is 150 mg QD for up to 6 months and the use of 200 mg BID is not recommended. Orilissa is contraindicated in

patients with severe hepatic impairment. Duration of therapy is limited due to the anti-estrogenic effects of the medication which include a decrease in bone mineral density.

Disease Overview

Endometriosis is a condition where the tissues similar to the lining of the uterus (or endometrium) migrate outside of the womb to other body sites.^{2,3} The migrated tissues are generally found in the pelvic cavity (e.g., peritoneum, uterosacral ligaments, rectal-vaginal septum, or any spaces between the bladder, uterus, vagina, and rectum) and can attach to any of the female reproductive organs (e.g., ovaries, fallopian tubes). The migrated tissue is less commonly found outside the pelvic cavity or on the intestines, colon, appendix or rectum. Endometriosis impacts up to 10% of patients of reproductive age in the US.³

Guidelines

According to the American College of Obstetricians and Gynecologists practice bulletin on the management of endometriosis (2010, reaffirmed 2018), after an appropriate pretreatment evaluation (to exclude other causes of chronic pelvic pain) and failure of initial treatment with oral contraceptives and nonsteroidal anti-inflammatory drugs (NSAIDs), empiric therapy with a 3-month course of a GnRH agonist is appropriate.²

Medical Necessity Criteria

Orilissa is considered medically necessary when the following criteria are met:

FDA-Approved Indication

- 1. Endometriosis.** Approve for 6 months if the patient meets ONE of the following (A or B):
 - A) Initial Therapy.** Approve if the patient has tried ONE of the following, unless contraindicated (i or ii):

Note: An exception to the requirement for a trial of the below therapies can be made if the patient had previously used a gonadotropin-releasing hormone agonist (e.g., Lupron Depot [leuprolide depot injection]) or Myfembree (relugolix, estradiol, norethindrone tablets) for endometriosis.

 - i.** A contraceptive (e.g., combination oral contraceptives, levonorgestrel-releasing intrauterine systems [e.g., Mirena {levonorgestrel intrauterine system}, Liletta {levonorgestrel intrauterine system}], a depo-medroxyprogesterone injection); OR
 - ii.** An oral progesterone (e.g., norethindrone tablets); OR
 - B) Patient is Currently Receiving Orilissa.** Approve.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven (criteria will be updated as new published data are available).

References

1. Orilissa™ tablets [prescribing information]. North Chicago, IL: AbbVie; June 2023.
2. Endometriosis. Endometriosis Foundation of America. Updated 9/28/2022. Available at: <https://www.endofound.org/endometriosis>. Accessed on April 5, 2024.
3. Global Forum. Endometriosis.org. Available at: <http://endometriosis.org/endometriosis/>. Accessed on April 5, 2024.
4. Management of Endometriosis. ACOG Practice Bulletin. Clinical Management Guidelines for Obstetrician-Gynecologists. Number 114, July 2010. (Reaffirmed 2018) *Obstetrics & Gynecology*. 2010;116(1):223-236.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	<p>Policy Name Change: Updated Policy Name from "Elagolix" to "Gonadotropin-Releasing Hormone Antagonists – Orilissa."</p> <p>Authorization Duration: Updated initial therapy duration from 12 months to 6 months for the treatment of Endometriosis.</p>	08/01/2024

The policy effective date is in force until updated or retired.

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