PRIOR AUTHORIZATION POLICY

POLICY: Gonadotropin-Releasing Hormone Antagonists – Orilissa Prior Authorization Policy
- Orilissa™ (elagolix tablets – AbbVie)

REVIEW DATE: 04/19/2024

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]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Orilissa. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

Automation: When available, the ICD-10 codes for endometriosis (N80 through N80.9) **AND** a prior therapy in the last 180 days which includes any one of the following: contraceptives (STCs 0248, 9654, and 9495), intrauterine devices (STC 4730), oral progestins (STC 0246 RT 01), depo-medroxyprogesterone injections (STC 4139), GnRH agonists (STC 8253, STC E851, STC 8254 STR 0190 RT 27), Myfembree, or Orilissa will be used to allow approval of the requested medication.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Orilissa is recommended in those who meet the following criteria:

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.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Orilissa is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. 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 Obstetrican-Gynecologists. Number 114, July 2010. (Reaffirmed 2018) *Obstetrics & Gynecology.* 2010;116(1):223-236.