PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 04/13/2022

OVERVIEW

Orilissa, an oral gonadotropin-releasing hormone (GnRH) receptor antagonist, is indicated for the management of moderate to severe pain associated with **endometriosis**.[1] In patients with normal liver function, the recommended dosage is 150 mg once daily for up to 24 months (no coexisting conditions) or 200 mg twice daily for up to 6 months (dyspareunia). In patients with moderate hepatic impairment (Child-Pugh Class B), the recommended dosage is 150 mg once daily for up to 6 months and the use of 200 mg twice daily dosing 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.

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 non-steroidal anti-inflammatory drugs (NSAIDs), empiric therapy with a 3-month course of a GnRH agonist is appropriate.[4]

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), 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, ii, or iii):
     - **i.** A contraceptive (e.g., combination oral contraceptives, levonorgestrel-releasing intrauterine systems [e.g., Mirena, Liletta]); OR
     - **ii.** An oral progesterone (e.g., norethindrone tablets); OR
     - **iii.** A depo-medroxyprogesterone injection.

       Note: An exception to the requirement for a trial of the above therapies can be made if the patient had previously used a gonadotropin-releasing hormone agonist (e.g., Lupron Depot) for endometriosis.
   - **B)** Patient 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; February 2021.
2. Endometriosis. Endometriosis Foundation of America. Available at https://www.endofound.org/endometriosis. Accessed on April 7, 2022.
3. Global Forum. Endometriosis.org. Available at http://endometriosis.org/endometriosis/. Accessed on April 7, 2022.
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.