STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES

Office of Pharmacy Services
Prior Authorization Criteria

Orilissa® (elagolix)

Effective 9/22/2021

Prior Authorization Request Form

Orilissa is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the management of moderate to severe pain associated with endometriosis.

Prior authorization requests for Orilissa may be approved if the following criteria are met:

1. The patient must be within the age range as recommended by the FDA label; **AND**
2. Patient must not be pregnant; **AND**
3. Patient does not have osteoporosis; **AND**
4. Patient does not have severe hepatic impairment; **AND**
5. Patient has failed to achieve significant symptomatic relief with NSAID therapy (please provide documentation); **AND**
6. Patient has failed a 90-day trial with one agent from ONE of the following categories (unless contraindicated):
    a. Extended-cycle combined oral contraceptive **OR** progestin therapy
    b. GnRH agonist

Approval Duration: Initial approval will be for 90 days.

Criteria for reauthorization:

1. Demonstrate continued documented compliance; **AND**
2. Patient has experienced clinically significant improvement in symptoms as compared to that seen using previous therapy.

Updated at DUR board meeting- 9/22/21 PS
Original DUR Board Approval: 11/20/2019

Continuation of therapy may be granted for up to 12 months. To reduce the extent of bone loss, the total duration of therapy shall not exceed the maximum limitations as outlined below:

Dosing Regimen	**Maximum treatment duration**	**Coexisting Condition**
Initiate treatment with Orilissa 150 mg once daily	24 months	None
Consider initiating treatment with Orilissa 200 mg twice daily	6 months	Dyspareunia
Initiate treatment with Orilissa 150 mg once daily. Use of 200 mg twice daily is not recommended.	6 months	Moderate hepatic impairment (Child-Pugh Class B)

References

1.) Orilissa Package Insert (7/2018), (9/2021)
2.) LexiComp monograph on Orilissa (reviewed 9/17/2018), (9/2021)
3.) UpToDate article on Endometriosis: Treatment of pelvic pain (reviewed 11/18/2019), (9/2021)
4.) ACOG updates guideline on diagnosis and treatment of endometriosis. Am Fam Physician. 2011 Jan 1;83(1):84-85
5.) Institute for Clinical and Economic Review Final Report Highlights Limitations in Evidence on Long-term Safety and Effectiveness of Elagolix for Endometriosis, Discusses Options for Insurance Coverage Criteria. August 3, 2018