

Generic Name: Elagolix

Therapeutic Class or Brand Name: Orilissa

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 3009003010

Preferred: N/A

Non-preferred: N/A

Date of Origin: 12/1/2018

Date Last Reviewed / Revised: 12/1/2018

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met)

- I. Documented diagnosis of moderate to severe pain associated with endometriosis.
- II. Documentation of patient's baseline hepatic function, and treatment duration and dose are appropriate for liver function (see Appendix).
- III. Documented trial and failure of, intolerance, or contraindication to ALL medication options A through C:
 - A. Nonsteroidal anti-inflammatory drugs (NSAIDs) for at least 3 months.
 - B. Oral hormonal contraceptives for at least 6 months.
 - C. Depot medroxyprogesterone.
- IV. Diagnosis must be established by a gynecologist or obstetrician.
- V. Minimum age requirement: 18 years old.

EXCLUSION CRITERIA

- Pregnancy.
- Known osteoporosis.
- Severe hepatic impairment (Child-Pugh C).
- Concurrent use of strong organic anion transporting polypeptide (OATP) 1B1 inhibitors (see Appendix).
- Male patients.

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- 150mg tablets
 - 30 tablets per 30 days

- 200mg tablets
 - 60 tablets per 30 days

APPROVAL LENGTH

- **Authorization:** 6 months.
- **Re-Authorization:** For 150mg once daily dosing only: Up to 18 months (until total lifetime treatment duration reaches 24 months). An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

APPENDIX

Dose Table

Liver Function	Dose Regimen
Normal liver function or mild hepatic impairment (Child-Pugh A)	150mg once daily for up to 24 months OR 200mg twice daily for up to 6 months
Moderate hepatic impairment (Child-Pugh B)	150mg once daily for up to 6 months

Examples of Strong OATP1B1 inhibitors:

- Atazanavir and ritonavir
- Clarithromycin
- Cyclosporine
- Erythromycin
- Gemfibrozil
- Lopinavir and ritonavir
- Rifampin
- Verapamil

REFERENCES

1. ACOG Updates Guideline on Diagnosis and Treatment of Endometriosis. <https://www.aafp.org/afp/2011/0101/p84.html>.
2. ESHRE guideline: management of women with endometriosis. <https://academic.oup.com/humrep/article/29/3/400/707776>.
3. Medi-Span®.

4. <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionsLabeling/ucm093664.htm>.
5. https://www.rxabbvie.com/pdf/orilissa_pi.pdf.

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
12/1/2018	1. New Policy.

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.