

**Generic Name:** Elagolix 300 mg, estradiol 1 mg, norethindrone acetate 0.5 mg; Elagolix

**Therapeutic Class or Brand Name:** Oriahnn, Orilissa

**Applicable Drugs (if Therapeutic Class):** GnRH Antagonists

**GPI Code:** 2499350340, 3009003010

**Preferred:** N/A

**Non-preferred:** N/A

**Date of Origin:** 12/1/2018

**Date Last Reviewed / Revised:** 10/7/2020

### PRIOR AUTHORIZATION CRITERIA

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

- I. Documented diagnosis of one of the following A or B and must meet the criteria under applicable diagnosis:
  - A. Orilissa™ for treatment of endometriosis
    1. Documentation of moderate to severe pain associated with endometriosis.
    2. Documented trial and insufficient response to at least 2 of the following:
      - a) Oral hormonal contraceptives or depot medroxyprogesterone for a minimum of 6 months.
      - b) Levonorgestrel releasing intra-uterine device (IUD).
      - c) Etonogestrel implant.
  - B. Oriahnn™ for treatment of heavy menstrual bleeding due to fibroids (uterine leiomyomas).
    1. Documented trial and insufficient response to at least 2 of the following:
      - a) Oral hormonal contraceptives for at least 6 months
      - b) Levonorgestrel releasing intra-uterine device (IUD).
      - c) Generic tranexamic acid.
- II. Documentation of patient's baseline hepatic function, and treatment duration and dose are appropriate for liver function (see Appendix).
- III. Diagnosis must be established by a gynecologist or obstetrician.
- IV. Minimum age requirement: 18 years old.

### EXCLUSION CRITERIA

- Pregnancy.
- Known osteoporosis.

- Liver Impairment (Orilissa approved in Child-Pugh A and B) (~~Severe hepatic impairment (Child-Pugh C).~~)
- Concurrent use with GnRH agonists
- Concurrent use of strong organic anion transporting polypeptide (OATP) 1B1 inhibitors (see Appendix).
- Male patients.

## OTHER CRITERIA

- N/A

## QUANTITY / DAYS SUPPLY RESTRICTIONS

- Oriahnn
  - 4 blister packs per 28 days.
- Orilissa
  - 150mg tablets, up to 30 tablets per 30 days
  - 200mg tablets, up to 60 tablets per 30 days

## APPROVAL LENGTH

- **Authorization:** 6 months.
- **Re-Authorization:**
  - Oriahnn (elagolix 300 mg, estradiol 1 mg, norethindrone acetate 0.5 mg)
    - An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.
    - Documentation of reason surgical intervention (hysteroscopic myomectomy) is contraindicated.
    - Up to 18 months (until total lifetime treatment duration reaches 24 months).
  - Orilissa:
    - 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.
    - 200 mg not authorized for renewal.

## APPENDIX

Dose Table- Orilissa

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

Dose Table- Oriahnn

Liver Function	Dose Regimen
Normal liver function	Elagolix 300 mg, estradiol 1 mg, norethindrone acetate 0.5 mg) in the morning and one capsule (elagolix 300 mg) in the evening for up to 24 months
Hepatic impairment (Child-Pugh A-C),	Contraindicated

Examples of Strong OATP1B1 inhibitors:

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

**REFERENCES**

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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>.
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9. Stein K, Ascher-Walsh C. A comprehensive approach to the treatment of uterine leiomyomata. Mt Sinai J Med. 2009 Dec;76(6):546-56. doi: 10.1002/msj.20145. PMID: 20014416.
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**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.