

Generic Name: Elagolix 300 mg, estradiol 1 mg, norethindrone acetate 0.5 mg; Elagolix; relugolix 40mg, estradiol 1mg, and norethindrone 0.5mg

Therapeutic Class or Brand Name: GnRH Antagonists

Applicable Drugs (if Therapeutic Class):
Oriahnn, Orilissa, Myfembree

Preferred: N/A

Non-preferred: N/A

Date of Origin: 12/1/2018

Date Last Reviewed / Revised: 8/14/2024

PRIOR AUTHORIZATION CRITERIA

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

- I. Documented diagnosis of one of the following A or B and must meet the criteria under applicable diagnosis:
 - A. Orilissa™ and Myfembree 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™ and Myfembree 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. Treatment must be prescribed by or in consultation with a gynecologist or obstetrician.
- IV. Minimum age requirement: 18 years old.
- V. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Pregnancy.
- Known osteoporosis.
- 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.
- Previous treatment with elagolix-containing product (e.g., Oriahnn, Orilissa, Myfembree) for greater than or equal to 24 cumulative months.

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
- Myfembree
 - 28 tablets per 28 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.
- Patients with moderate hepatic impairment (Child-Pugh B) not authorized for renewal.
- Myfembree (relugolix 40mg, estradiol 1mg, and norethindrone 0.5mg)
 - 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).

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
Moderate hepatic impairment (Child-Pugh B)	Elagolix 150mg once daily for up to 6 months
Dyspareunia	Elagolix 200 mg twice 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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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.