Applicable Drugs: Myfembree (relugolix-estradiol-norethindrone acetate), Oriahnn (elagolix-estradiol-norethindrone & elagolix), Orilissa (elagolix sodium)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 12/1/2018

Date Last Reviewed / Revised: 10/15/2026

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. Treatment must be prescribed by or in consultation with a gynecologist or obstetrician.

III. Minimum age requirement: 18 years old.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

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 (such as atazanavir and ritonavir, clarithromycin, cyclosporine, gemfibrozil, lopinavir and ritonavir, and rifampin).
- Male patients.
- Previous treatment with elagolix-containing product (such as Oriahnn, Orilissa, Myfembree) for greater than or equal to 24 cumulative months.
- Oriahnn and Myfembree: current or a history of thrombotic or thromboembolic disorders and in women at increased risk for these events, including women over 35 years of age who smoke or women with uncontrolled hypertension.

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Refer to Table 1 GnRH Antagonists FDA-Recommended Dosage and Administration, Quantity, and Days Supply Restrictions in Appendix.

APPROVAL LENGTH

- **Authorization:** 6 months.
- **Re-Authorization:**
    - Oriahnn:
        - 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 twice daily dosing are not authorized for renewal.
- Patients with moderate hepatic impairment (Child-Pugh B) are not authorized for renewal.

- Myfembree:
  - 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 to18 months (until total lifetime treatment duration reaches 24 months).

APPENDIX

Table 1 GnRH Antagonist FDA-Recommended Dosage and Administration, Quantity, and Days Supply Limits

Brand (Generic)	Dosing	Quantity and Days Supply Restrictions
Oriahnn (elagolix, estradiol, and norethindrone acetate; elagolix)	Normal liver function: • One capsule (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, B, and C) • Contraindicated	56 capsules/28 days.
Orilissa (elagolix)	Normal liver function or mild hepatic impairment (Child-Pugh A) without coexisting dyspareunia: • One tablet (150 mg) once daily for up to 24 months. Normal liver function or mild hepatic impairment (Child-Pugh A) with coexisting dyspareunia: • One tablet (200 mg) twice daily for up to 6 months	150mg tablets: up to 28 tablets/28 days 200mg tablets: up to 56 tablets/28 days

	Moderate hepatic impairment (Child-Pugh B): • One tablet (150 mg) once daily for up to 6 months Severe hepatic impairment (Child-Pugh C): • Contraindicated	
Myfembree (relugolix, estradiol, norethindrone acetate)	Normal liver function: • One tablet (relugolix 40 mg, estradiol 1 mg and norethindrone acetate 0.5 mg) once daily. Hepatic impairment (Child-Pugh A, B, and C) • Contraindicated	28 tablets/28 days

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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.