Mass General Brigham
Health Plan

Elagolix and Relugolix Containing Products
Orilissa (elagolix)
Oriahnn (elagolix, estradiol, and norethindrone acetate)
Myfembree (relugolix, estradiol, norethindrone acetate)
Effective 11/01/2025

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview

Orilissa (elagolix) is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the management of moderate to severe pain associated with endometriosis. Orilissa should be used at the lowest effective dose, and severity of symptoms and treatment objectives should be taken into account. Duration of use should be limited due to bone loss.

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)

Oriahnn (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules) is indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women. The recommended dosage for Oriahnn is 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. Use of Oriahnn should be limited to 24 months due to the risk of continued bone loss, which may not be reversible.

Myfembree (relugolix, estradiol, and norethindrone acetate) tablet is indicated for the:

- management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women.
- management of moderate to severe pain associated with endometriosis

Myfembree is administered as one tablet once daily. Use of Myfembree should be limited to 24 months due to the risk of continued bone loss which may not be reversible.

Coverage Guidelines

Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted when all the following diagnosis-specific criteria are met:

Endometriosis with Moderate to Severe Pain

Myfembree and Orilissa

1. Documented diagnosis of endometriosis with moderate to severe pain
2. Member is 18 years of age or older
3. Member has had an insufficient response or intolerance to generic alternatives in at least two or contraindication to all of the following therapeutic drug classes:
    a. Nonsteroidal anti-inflammatory drugs (NSAIDs)
    b. Hormonal contraceptives
    c. Oral or depot medroxyprogesterone
4. The member has had an inadequate response, adverse reaction, or contraindication to Lupron

Uterine Fibroids

Oriahnn and Myfembree

1. Member is premenopausal
2. Documented diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids)
3. Member is 18 years of age or older
4. Member has had inadequate response, intolerance or contraindication to ALL of the following:
    a. A hormonal contraceptive method (e.g. combined estrogen progestin contraceptive, levonorgestrel intrauterine devices, or progestin-only contraceptive)
    b. Generic tranexamic acid tablet

Limitations

1. Approval durations are as follows:

Medication	Diagnosis	Duration of Approval
Orilissa 150mg	Endometriosis without dyspareunia	24 months
Orilissa 200mg	Endometriosis with dyspareunia	6 months
Oriahnn 300mg-1-0.5 & 300mg	Heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women	24 months
Myfembree	1. Heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women 2. Endometriosis	24 months Use of relugolix containing products should be limited to 24 months.

2. Reauthorizations will not be granted per manufacture recommended treatment guidelines
3. Myfembree has a quantity limit of 1 tablet per day.

References

1. Myfembree (relugolix, estradiol, and norethindrone) [prescribing information]. Marlborough, MA: Sumitomo Pharma America, Inc; July 2024.
2. Oriahnn (elagolix, estradiol, and norethindrone) [prescribing information]. North Chicago, IL: Abbvie Inc; June 2023.
3. Orilissa (elagolix) [prescribing information]. North Chicago, IL: AbbVie Inc; June 2023.
4. Struthers RS, Nicholls AJ, Grundy J, et al. Suppression of gonadotropins and estradiol in premenopausal women by oral administration of the nonpeptide gonadotropin-releasing hormone antagonist elagolix. *J Clin Endocrinol Metab*. 2009;94(2):545-551. doi:10.1210/jc.2008-1695. [PubMed 19033369]
5. Surrey E, Taylor HS, Giudice L, et al. Long-Term Outcomes of Elagolix in Women With Endometriosis: Results From Two Extension Studies. Obstet Gynecol 2018; 132:147.
6. Taylor HS, Giudice LC, Lessey BA, et al. Treatment of Endometriosis-Associated Pain with Elagolix, an Oral GnRH Antagonist. N Engl J Med 2017; 377:28.

Review History

02/20/2019 – Reviewed

09/16/2020 – Reviewed and Updated; added new medication Oriahnn, references updated; added QL to program for Orilissa and Oriahnn; Maximum approval included in limitations. Effective 11/01/20.

09/22/2021 – Reviewed and Updated; added new medication Myfembree; references updated. Effective 11/01/2021.

08/09/2025 – Reviewed and updated at August P&T. Added criteria for members who are new to the Plan. Updated criteria to include Myfembree's supplemental indication of endometriosis. Updated criteria to require that diagnoses are documented. Updated criteria for trial requirements to include contraindication to all agents. Effective 11/01/2025.