Mass General Brigham
Health Plan

Elagolix and Relugolix Containing Products
Orilissa (elagolix)
Oriahnn (elagolix, estradiol, and norethindrone acetate)
Myfembree (relugolix, estradiol, norethindrone acetate)
Effective 11/01/2021

<table>
<tr><td>Plan</td><td>☐ MassHealth UPPL
☒Commercial/Exchange</td><td rowspan="2">Program Type</td><td rowspan="2">☒ Prior Authorization
☐ Quantity Limit
☐ Step Therapy</td></tr>
<tr><td>Benefit</td><td>☒ Pharmacy Benefit
☐ Medical Benefit</td></tr>
<tr><td>Specialty Limitations</td><td colspan="3">N/A</td></tr>
<tr><td rowspan="4">Contact Information</td><td colspan="3">Medical and Specialty Medications</td></tr>
<tr><td>All Plans</td><td>Phone: 877-519-1908</td><td>Fax: 855-540-3693</td></tr>
<tr><td colspan="3">Non-Specialty Medications</td></tr>
<tr><td>All Plans</td><td>Phone: 800-711-4555</td><td>Fax: 844-403-1029</td></tr>
<tr><td>Exceptions</td><td colspan="3">N/A</td></tr>
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Overview

Orilissa (elagolix) is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the management of moderate to severe pain associated with endometriosis.

Oriahnn (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules) is a combination of elagolix, a gonadotropin-releasing hormone (GnRH) receptor antagonist, estradiol, an estrogen, and norethindrone acetate, a progestin, indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women.

Myfembree (relugolix, estradiol, and norethindrone acetate) tablet is indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women.

Coverage Guidelines

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

Orilissa

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

Oriahnn and **Myfembree**

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

Limitations

- Approvals will be granted for the following:

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	Heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women	24 months Use of relugolix containing products should be limited to 24 months.

- Reauthorizations will not be granted per manufacture recommended treatment guidelines

References

1. Orilissa (elagolix) [prescribing information]. North Chicago, IL: AbbVie Inc; July 2018.
2. 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.
3. 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.
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. Oriahnn (elagolix, estradiol, and norethindrone) [prescribing information]. North Chicago, IL: Abbvie Inc; May 2020.
6. Myfembree (relugolix, estradiol, and norethindrone) [prescribing information]. Brisbane, CA: Myovant Sciences Inc; May 2021.

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.