

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

<b>Plan</b>	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		
<b>Specialty Limitations</b>	N/A		
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	<b>Non-Specialty Medications</b>		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	<b>Medical Specialty Medications (NLX)</b>		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
<b>Exceptions</b>	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.

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  $\geq 18$  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.

