GnRH Analogues
Myfembree® (relugolix, estradiol, norethindrone)
Oriahnn® (elagolix, estradiol, norethindrone)
Orilissa® (elagolix)
Effective 02/01/2023

Plan	☒ MassHealth ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	N/A		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	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
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

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

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.

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

No PA	Drugs that require PA
	Myfembree® (relugolix/estradiol/norethindrone)
	Oriahnn® (elagolix/estradiol/norethindrone)
	Orilissa® (elagolix)

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

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

Uterine leiomyomata (fibroids)
Myfembree (relugolix/estradiol/norethindrone)
Oriahnn (elagolix/estradiol/norethindrone)
Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Anticipated surgery date or clinical rationale why surgical intervention is not appropriate
3. Physician documentation of inadequate response or adverse reaction to one hormonal contraceptive, or contraindication to all hormonal contraceptives
4. For requests for **Oriahnn**, ALL of the following:
    a. Physician documentation of inadequate response, adverse reaction, or contraindication to Lupron
    b. Request is within quantity limit of two units/day
    c. Duration of total therapy is limited to ≤ 24 months
5. For requests for **Myfembree**, ALL of the following:
    a. Physician documentation of inadequate response, adverse reaction, or contraindication to Lupron and Oriahnn
    b. Request is within quantity limit of one unit/day
    c. Duration of total therapy is limited to ≤ 24 months
6. Appropriate dose and frequency

Endometriosis
Orilissa (elagolix)
Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Physician documentation of inadequate response or adverse reaction to one NSAID, or contraindication to all NSAIDs
3. Physician documentation of inadequate response or adverse reaction to one hormonal contraceptive, or contraindication to all hormonal contraceptives
4. Physician documentation of inadequate response, adverse reaction, or contraindication to Lupron
5. Appropriate dose and frequency

Continuation of Therapy
Reauthorization requires physician documentation of a positive response to therapy.

Endometriosis: Reauthorization by physician will infer a positive response to therapy. For Orilissa only: If member has dyspareunia or moderate hepatic impairment (Child-Pugh Class B)

Limitations

1. Initial approvals will be granted for:
    a. Uterine leiomyomata (fibroids): up to 6 months (shorter duration if surgery is planned within the next 6 months). Total therapy duration should not exceed 24 months.
    b. Endometriosis: 12 months
        i. Orilissa only – total of 6 months if dyspareunia or moderate hepatic impairment (Child-Pugh Class B)
2. Reauthorizations will be granted for:

a. Uterine leiomyomata (fibroids): up to 6 months (shorter duration if surgery is planned within the next 6 months). Total therapy duration should not exceed 24 months.
b. Endometriosis: 12 months
    i. Orilissa only – total of 6 months if dyspareunia or moderate hepatic impairment (Child-Pugh Class B)

3. The following quantity limits apply:

Myfembree oral tablet	30 tablets per 30 days
Oriahnn oral capsule	60 capsules per 30 days

References

1. Orilissa® [package insert on the Internet]. North Chicago, IL: AbbVie; 2018 Jul.
2. Oriahnn® (elagolix, estradiol, norethindrone acetate) [package insert on the internet]. North Chicago (IL): AbbVie, Inc; 2020 May
3. Myfembree® (relugolix/estradiol/norethindrone acetate) [package insert on the internet]. Brisbane (CA): Myovant Sciences; 2021 May.
4. Stewart EA. Overview of treatment of uterine leiomyomas (fibroids). In: Basow DS (Ed). UptoDate [database on the Internet]. Waltham (MA): UptoDate; 2017 [cited 2017 Nov 27]. Available from: http://www.utdol.com/utd/index.do.
5. Welt CK. Physiology of gonadotropin-releasing hormone. In: Basow DS (Ed). UptoDate [database on the Internet]. Waltham (MA): UptoDate; 2017 [cited 2017 Nov 27]. Available from: http://www.utdol.com/utd/index.do.
6. Martin TJ, Gaddy D. Bone loss goes beyond estrogen. Nature Medicine 2006 (12); 612-13. Available from: http://www.nature.com/nm/journal/v12/n6/pdf/nm0606-612.pdf
7. Hornstein M, Gibbons W. Gonadotropin releasing hormone agonists for long term treatment of endometriosis. In: Basow DS (Ed). UptoDate [database on the Internet]. Waltham (MA): UptoDate; 2017 [cited 2017 Nov 27]. Available from: http://www.utdol.com/utd/index.do.
8. 38. American College of Obstetricians and Gynecologists. ACOG committee opinion no. 557: Management of acute abnormal uterine bleeding in nonpregnant reproductive-aged women. Obstet Gynecol. 2013;121(4):891- 896.
9. Maybin JA, Critchley HO. Medical management of heavy menstrual bleeding. Womens Health (Lond). 2016;12(1):27-34.
10. Shore ND, Saad F, Cookson MS, George DJ, Saltzstein DR, Tutrone R, et al. Oral Relugolix for Androgen-Deprivation Therapy in Advanced Prostate Cancer. N Engl J Med. 2020 Jun 4;382(23):2187-2196. doi: 10.1056/NEJMoa2004325. Epub 2020 May 29.
11. UpToDate. Drug Information Reference Database. UpToDate [database on the internet]. Waltham (MA): UpToDate; accessed 2021 May 7. Available from: https://www.uptodate.com/contents/table-of-contents/drug-information.

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
11/16/2022 – Reviewed and updated for Nov P&T. Separated out Comm/Exch vs MH. Matched MH UPPL criteria. Effective 2/1/23

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