Orilissa™ (elagolix), Oriahnn™ (elagolix, estradiol, norethindrone acetate), Myfembree® (relugolix, estradiol, and norethindrone acetate)

FDA INDICATIONS AND USAGE[1,3]

Orilissa™ is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the management of severe pain associated with endometriosis. Oriahnn™ is indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women. Myfembree® is a combination of relugolix, 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.

APPROVAL CRITERIA[1,2,3,4]

Orilissa™

1. Patient is 18-49 years of age **AND**;
2. Patient has a diagnosis of endometriosis **AND;**
3. Patient is not taking a strong organic anion transporting polypeptide 1B1 inhibitor (i.e. cyclosporine) **AND;**
4. Patient has had an adequate trial of an oral combination contraceptive for at least 3 months **AND;**
5. Patient has had a trial of NSAID product for at least 1 month.

Oriahnn™

1. Patient is 18 years of age or older **AND;**
2. Patient has been diagnosed with uterine leiomyomas (fibroids) **AND;**
3. Medication is being used for heavy menstrual bleeding **AND;**
4. Patient does not have a history of thrombotic or thromboembolic disorders **AND;**
5. Patient is not taking a strong organic anion transporting polypeptide 1B1 inhibitor (i.e. cyclosporine) **AND;**
6. Patient has had an adequate trial of an oral contraceptive or oral progesterone for at least 3 months **AND;**
7. Patient has had a trial of NSAID product for at least 1 month.

ALASKA MEDICAID
Prior Authorization Criteria

Myfembree®

1. Patient is 18 years of age or older **AND;**
2. Patient has been diagnosed with uterine leiomyomas (fibroids) **AND;**
3. Medication is being used for heavy menstrual bleeding **AND;**
4. Patient does not have a history of thrombotic or thromboembolic disorders **AND;**
5. Patient is not taking with oral P-glycoprotein inhibitors. (i.e. amiodarone, verapamil, etc.) **AND;**
6. Patient has had an adequate trial of an oral contraceptive or oral progesterone for at least 3 months **AND;**
7. Patient has had a trial of NSAID product for at least 1 month.

DENIAL CRITERIA[1,2,3]

1. Failure to meet approval criteria **OR;**
2. Patient is pregnant **OR;**
3. Patient has known osteoporosis **OR;**
4. Patient has known hepatic impairment or liver disease.

CAUTIONS[1]

- Elagolix may be associated with potentially irreversible bone loss.
- May reduce the ability to recognize pregnancy.
- May increase suicidal ideation and mood disorders.
- May increase liver transaminases and should be monitored.
- Has the potential to decrease efficacy of estrogen containing contraceptives.

DURATION OF APPROVAL[1,3,4]

- Initial Approval: up to 6 months
- Reauthorization Approval for Orilissa™: up to 12 months for 150mg dose only
- Reauthorization Approval for Oriahnn™: up to 12 months (not to exceed 24 months total duration of treatment)
- Reauthorization Approval for Myfembree®: up to 12 months (not to exceed 24 months total duration of treatment)

QUANTITY LIMITS

- 30 – 150mg tablets per month (Orilissa™)
- 60 – 200mg tablets per month (Orilissa™)
- 56 capsules contained in 4 blister packs (Oriahnn™)
- 30 capsules per 30 days (Myfembree®)

REFERENCES / FOOTNOTES:

1. Orilissa™ (elagolix) [prescribing information]. North Chicago, IL: AbbVie Inc.; July 2018. Available at: https://www.rxabbvie.com/pdf/orilissa_pi.pdf. Accessed September 2018.
2. Schrager S, Falleroni J, Edgoose J. Evaluation and Treatment of Endometriosis. American Family Physician. 2013 Jan 15;87(2):107-113.
3. Oriahnn™ [package insert]. North Chicago, IL: AbbVie Inc.; Revised 05/2020.
4. Myfembree®[package insert]. Brisbane, CA: Myovant Sciences, Inc. Revised 05/2021.