Louisiana Medicaid
Uterine Disorder Treatments

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for uterine disorder treatment agents.

Additional Point-of-Sale edits may apply.

*These agents may have a **Black Box Warning(s)** and may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*

Elagolix and relugolix are gonadotropin-releasing hormone (GnRH) receptor antagonists. Use of these agents should be limited to 24 months (or less depending on the agent, dosage and coexisting conditions) due to the risk of continued bone loss, which may not be reversible.

Elagolix (Orilissa®)

Approval Criteria

- The recipient is 18 years of age or older on the date of the request**; AND**
- The recipient has been diagnosed with moderate-to-severe pain associated with endometriosis; **AND**
- The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a gynecologist; **AND**
- The prescriber states the recipient's level of hepatic impairment on the request. [For approval, it must be NONE, mild, or moderate]; **AND**
- **ONE** of the following:
    - The recipient has a history of at least a 3-month trial and inadequate response to at least one non-steroidal anti-inflammatory agent (NSAID); **OR**
    - The recipient has a contraindication or intolerance to NSAIDS; **AND**
- **ONE** of the following:
    - The recipient has a history of at least a 3-month trial and inadequate response to a progestin or a hormonal contraceptive; **OR**
    - The recipient has a contraindication or intolerance to progestins and hormonal contraceptives; **AND**
- **ONE** of the following:
    - The recipient is naïve to elagolix (Orilissa®); **OR**
    - The recipient is receiving 150mg once daily, has no coexisting conditions, and has utilized elagolix (Orilissa®) for a combined total duration of less than 24 months in their lifetime; **OR**

    - The recipient is receiving 150mg once daily, has moderate hepatic impairment (Child-Pugh class B), and has utilized elagolix (Orilissa®) for a combined total duration of less than 6 months in their lifetime; **OR**
    - The recipient is receiving 200mg twice daily, has dyspareunia, and has utilized elagolix (Orilissa®) for a combined total duration of less than 6 months in their lifetime; **AND**
- For a non-preferred agent, there is no preferred alternative that is the exact same chemical entity, formulation, strength, etc; **AND**
- For a non-preferred agent, previous use of a preferred product - **ONE** of the following is required:
    - The recipient has had *treatment failure* with at least one preferred product; **OR**
    - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
    - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate for the condition being treated; **OR**
    - There is *no preferred product that is appropriate* to use for the condition being treated; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of elagolix and will not be receiving elagolix in combination with any medication that is contraindicated or not recommended per FDA labeling.

Reauthorization Criteria

- The recipient has experienced clinically significant improvement in endometriosis-associated pain, which is **stated on the request**; **AND**
- The recipient is using 150mg once daily; **AND**
- The recipient has no coexisting conditions.

Duration of initial and reauthorization approval: up to 12 months*

Not to exceed the following lifetime maximum treatment durations with elagolix:

24 months for 150mg dose for recipient with no coexisting conditions
6 months for 150mg dose for recipient with moderate hepatic impairment
6 months for the 200mg dose

**Not to exceed a total of 24 months lifetime maximum treatment duration with products containing elagolix or relugolix.*

Elagolix, Estradiol, and Norethindrone acetate capsules; Elagolix capsules (Oriahnn®)

Approval Criteria

- The recipient is 18 years of age or older on the date of the request**; AND**
- The recipient has been diagnosed with heavy menstrual bleeding associated with uterine leiomyomas (fibroids); **AND**
- The prescriber **states on the request** that the recipient is premenopausal; **AND**
- The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a gynecologist; **AND**
- The recipient has a documented failure of, or intolerance to, or contraindication to treatment with progestins and hormonal contraceptives; **AND**
- For a non-preferred agent, there is no preferred alternative that is the exact same chemical entity, formulation, strength, etc; **AND**
- For a non-preferred agent, previous use of a preferred product - **ONE** of the following is required:
    - The recipient has had *treatment failure* with at least one preferred product; **OR**
    - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
    - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate for the condition being treated; **OR**
    - There is *no preferred product that is appropriate* to use for the condition being treated; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- The recipient has not exceeded a total of 24 months treatment duration with Oriahnn®; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of initial and reauthorization approval: up to 12 months*
**Not to exceed a total of 24 months lifetime maximum treatment duration with products containing elagolix or relugolix.*

Relugolix, Estradiol, Norethindrone Acetate (Myfembree®)

Approval Criteria

- The recipient is 18 years of age or older on the date of the request**; AND**
- The recipient has been diagnosed with **ONE** of the following:
    - Hheavy menstrual bleeding associated with uterine leiomyomas (fibroids); **OR**
    - **AND** Moderate to severe pain associated with endometriosis; **AND**
- The prescriber **states on the request** that the recipient is premenopausal; **AND**
- The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a gynecologist; **AND**
- The recipient has a documented failure of, or intolerance to, or contraindication to treatment with progestins and hormonal contraceptives; **AND**
- For a non-preferred agent, there is no preferred alternative that is the exact same chemical entity, formulation, strength, etc; **AND**
- For a non-preferred agent, previous use of a preferred product - **ONE** of the following is required:
    - The recipient has had *treatment failure* with at least one preferred product; **OR**
    - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
    - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate for the condition being treated; **OR**
    - There is *no preferred product that is appropriate* to use for the condition being treated; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- The prescriber **states on the request** that the recipient has not exceeded a total of 24 months duration of treatment with GnRH receptor antagonists; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of initial and reauthorization approval: up to 12 months*
**Not to exceed a total of 24 months lifetime maximum treatment duration with products containing elagolix or relugolix.*

References

American College of Obstetricians and Gynecologists. Management of Endometriosis. Practice Bulletin 114. July 2010

Myfembree (relugolix/estradiol hemihydrate/norethindrone acetate) [package insert]. Brisbane, CA: Myovant Sciences; August~~May~~ 2021. https://www.myovant.com/wp-content/uploads/2021/05/Approved-MYFEMBREE-PI-and-PPI_26May2021.pdf

Oriahnn (elagolix and estradiol/norethindrone) [package insert]. North Chicago, IL: AbbVie Inc; August 2021. https://www.rxabbvie.com/pdf/oriahnn_pi.pdf

Orilissa (elagolix) [package insert]. North Chicago, IL: AbbVie Inc; February 2021. https://www.rxabbvie.com/pdf/orilissa_pi.pdf

UpToDate: Endometriosis: Treatment of pelvic pain. Current through July~~September~~ 2021. www.uptodate.com

UpToDate: Uterine Fibroids (Leiomyomas); Treatment Overview. Current through September 2021. www.uptodate.com

Revision / Date	**Implementation Date**
Orilissa® policy created	May 2019
Added Oriahnn® criteria, updated references, formatting changes / April 2021	October 2021
Added Myfembree® with reference, clarified hepatic impairment criteria for Orilissa® / September 2021	January 2022
Added indication of endometriosis to Myfembree®, updated references / August 2022	January 2023