Louisiana ~~Fee-for-Service~~ Medicaid
Uterine Disorder Treatments

~~Elagolix (Orilissa®)~~

~~Elagolix (Orilissa®) requires clinical authorization.~~ The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for ~~elagolix (Orilissa®)~~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 (Orilissa®)

~~Requests for initial approval must meet the following criteria:~~Approval Criteria

- The ~~R~~recipient is 18 years of age or older on the date of the request**; AND**
- ~~Elagolix (Orilissa®) is being prescribed by a gynecologist**; AND**~~
- The ~~R~~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**
- ~~Elagolix (Orilissa®) is being prescribed by a gynecologist**; AND**~~
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- The ~~R~~recipient **DOES NOT** have severe hepatic impairment; **AND**
- **ONE** of the following:
  - The ~~R~~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 ~~R~~recipient has a contraindication or intolerance to NSAIDS; **AND**
- **ONE** of the following:
  - The ~~R~~recipient has a history of at least a 3-month trial and inadequate response to a progestin or a hormonal contraceptive; **OR**
  - The ~~R~~recipient has a contraindication or intolerance to progestins and hormonal contraceptives; **AND**
- **ONE** of the following:
  - The ~~R~~recipient is naïve to elagolix (Orilissa®); **OR**
  - The ~~R~~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 ~~R~~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 Rrecipient 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**
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- 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.

~~Requests for reauthorization with elagolix (Orilissa®) must meet the following criteria:~~ Reauthorization Criteria

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

Duration of ~~both~~ initial and reauthorization approval: Up to 12 months

~~Up to 12 months~~

Not to exceed the following lifetime maximum treatment durations:

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

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**
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- 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 ~~both~~ initial and reauthorization approval: 12 months
Not to exceed the lifetime maximum treatment duration of 24 months

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References

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

Oriahnn (elagolix and estradiol/norethindrone) [package insert]. North Chicago, IL: AbbVie Inc; May 2020. https://www.rxabbvie.com/pdf/oriahnn_pi.pdf

Orilissa® (elagolix) [package insert]. North Chicago, IL: AbbVie Inc; February 2021~~2018~~. https://www.rxabbvie.com/pdf/orilissa_pi.pdf~~Retrieved from~~

~~Sabry, M, Al-Hendy, Ayman. Medical Treatment of Uterine Leiomyoma. Reprod Sci. 2012:19(4):339-53.~~

UpToDate: Endometriosis: Treatment of pelvic pain. Current through April 2019.- www.uptodate.com

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

Revision / Date	**~~Date~~Implementation Date**
Orilissa® policy created~~.~~	May 2019
Added Oriahnn® criteria, updated references, formatting changes / April 2021	~~April 2021~~