Clinical Policy: Elagolix (Orilissa), Elagolix/Estradiol/Norethinedrone (Oriahnn)

Reference Number: IN.CP.PHAR.136
Effective Date: 01.01.2022
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Line of Business: Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Elagolix (Orilissa™) is a gonadotropin-releasing hormone (GnRH) receptor antagonist.

Elagolix/estradiol/norethinedrone; elagolix (Oriahnn™) is a combination of a GnRH receptor antagonist with an estrogen and progestin.

FDA Approved Indication(s)

Orilissa is indicated for the management of moderate to severe pain associated with endometriosis.

Oriahnn is indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women.

Limitation(s) of use: Use of Oriahnn should be limited to 24 months due to the risk of continued bone loss, which may not be reversible.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Oriahnn (ELAGOLIX/ESTRADIOL/NORETHINDRONE ACETATE) (must meet all)**:**

1. Diagnosis of menorrhagia associated with uterine leiomyomas (fibroids) in premenopausal females
2. Previous trial and failure of hormonal contraceptives/therapy (oral tablets, vaginal ring, patch, intrauterine contraception (IUD))
3. Age ≥ 18 years
4. Must have a negative pregnancy test in the past 30 days
5. Must have laboratory tests confirming no hepatic disease
6. Must have had a bone mineral density test negative for osteopenia or osteoporosis in the past 6 months
7. None of the following contraindications to therapy (a or b):

a. Concurrent use of organic anion transporting polypeptide (OATP)1B1 inhibitors that are known or expected to significantly increase elagolix plasma concentrations (e.g., cyclosporine, gemfibrozil)
b. Current diagnosis or history of breast cancer or other hormone-sensitive malignancies,
c. Increased risk factors for hormone-sensitive malignancies
d. Current diagnosis of, risk factors for, or previous history of thromboembolic disorders or vascular events
e. Undiagnosed abnormal uterine bleeding

8. Requested dose does not exceed 2 capsules (1 X 300/1/0.5mg; 1 X 300mg) per day.

Approval duration: 12 months

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B. ORILISSA (ELAGOLIX) (must meet all)**:**

1. One of the following:
    a. Diagnosis of moderate to severe pain associated with endometriosis AND the following• Requested dose does not exceed 150mg daily (1 year approval)
    b. Diagnosis of moderate to severe pain associated with endometriosis with co-existing endometriosis-related dyspareunia AND the following: • Requested dose does not exceed 400mg daily (6-month approval maximum);
2. Age ≥ 18 years;
3. One of the following:
    a. Previous trial and failure of hormonal contraceptives/therapy (oral tablets, vaginal ring, patch, intrauterine contraception (IUD)) AND NSAID therapy
    b. Prescriber has submitted valid medical rationale against the use of hormonal contraceptives/therapy AND/OR NSAID therapy
4. Must have a negative pregnancy test in the past 30 days
5. Must have laboratory tests confirming no hepatic disease worse than Child-Pugh A in the past 30 days - Adjusted dosing may be approved with Child-Pugh B hepatic disease (see Note)
6. Must have had a bone mineral density test negative for osteopenia or osteoporosis in the past 6 months
7. None of the following contraindications to therapy:
    a. Concurrent use of organic anion transporting polypeptide (OATP)1B1 inhibitors that are known or expected to significantly increase elagolix plasma concentrations (e.g., cyclosporine, gemfibrozil)
8. Dose does not exceed 600 mg of elagolix per day.

Approval duration: 12 months
Total duration of therapy should not exceed 24 months.

Note: Members with Child-Pugh class B hepatic impairment will be limited to the 150mg daily dose for a maximum of 6 months irrespective of indication

C. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

II. Continued Therapy

A. ORIAHNN (ELAGOLIX/ESTRADIOL/NORETHINDRONE ACETATE) (must meet all):
1. History of the requested agent within the past 90 days
2. Member will not be exceeding 24 months of therapy per lifetime with elagolix/estradiol/norethindrone acetate
3. Prescriber states that member remains a candidate for treatment, indicating that they have not developed any of the contraindication(s) listed in initial authorization criteria.

Approval duration: up to 12 months

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B. ORILISSA (ELAGOLIX) (must meet all):
1. History of the requested agent within the past 90 days;
2. Member will not be exceeding 24 months of therapy per lifetime with elagolix;
3. Prescriber states that member remains a candidate for treatment, indicating that they have not developed any of the contraindication(s) listed in initial authorization criteria
4. If request is for a dose increase, new dose does not exceed 600 mg of elagolix per day.

Approval duration: up to 12 months
Total duration of therapy should not exceed 24 months.

C. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
GnRH: gonadotropin-releasing hormone
OATP: organic anion transporting polypeptide

Appendix B: Therapeutic Alternatives

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Pregnancy
  - Known osteoporosis
  - Severe hepatic impairment
  - Concomitant use of strong organic anion transporting polypeptide (OATP) 1B1 inhibitors (e.g., cyclosporine and gemfibrozil)
  - Oriahnn only:
    - With a high risk of arterial, venous thrombotic, or thromboembolic disorders. Examples include women over 35 years of age who smoke, and women who are known to have:
      - Current or history of deep vein thrombosis or pulmonary embolism
      - Vascular disease (e.g., cerebrovascular disease, coronary artery disease, peripheral vascular disease)
      - Thrombogenic valvular or thrombogenic rhythm diseases of the heart (for example, subacute bacterial endocarditis with valvular disease, or atrial fibrillation)
      - Inherited or acquired hypercoagulopathies
      - Uncontrolled hypertension
      - Headaches with focal neurological symptoms or have migraine headaches with aura if over age 35
    - With current or history of breast cancer or other hormonally-sensitive malignancies, and with increased risk for hormonally-sensitive malignancies
    - With undiagnosed abnormal uterine bleeding
    - With known anaphylactic reaction, angioedema, or hypersensitivity to Oriahnn or any of its components
- Boxed warning(s):
  - Orilissa: None reported
  - Oriahnn: Thromboembolic disorders and vascular events

IV. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Elagolix (Orilissa)	Endometriosis pain	150 mg PO QD or 200 mg PO BID	150 mg/day x 24 months or 400 mg/day x 6 months
Elagolix/estradiol/ norethinedrone; elagolix (Oriahnn)	Heavy menstrual bleeding due to uterine fibroids	PO for up to 24 months: one capsule (elagolix 300 mg, estradiol 1 mg, norethindrone acetate 0.5 mg) in the morning and one capsule (elagolix 300 mg) in the evening	See regimen

V. Product Availability

Drug Name	Product Availability
Elagolix (Orilissa)	Tablets: 150 mg, 200 mg
Elagolix/estradiol/ norethinedrone; elagolix (Oriahnn)	Morning (AM) capsule: elagolix 300 mg, estradiol 1 mg, norethindrone acetate 0.5 mg Evening (PM) capsule: elagolix 300 mg

VI. References

1. Orilissa Prescribing Information. North Chicago, IL: AbbVie Inc.; February 2021. Available at: http://www.orilissa.com. Accessed June 21, 2021.
2. Oriahnn Prescribing Information. North Chicago, IL: AbbVie Inc.; May 2020. Available at: http://www.oriahnn.com. Accessed June 21.2021.
3. American College of Obstetricians and Gynecologists. Practice bulletin: clinical management guidelines for obstetrician-gynecologist: management of endometriosis. Am J Obstet Gynecol 2010;116(1):223-236.
4. American College of Obstetricians and Gynecologists. Practice bulletin: clinical management guidelines for obstetrician-gynecologist: alternatives to hysterectomy in the management of leiomyomas. Am J Obstet Gynecol. 2008;112(2):387-400.
5. American College of Obstetricians and Gynecologists. Practice bulletin: management of symptomatic uterine leiomyomas. Am J Obstet Gynecol. 2021;137(6):e100-e115.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created for IN Medicaid Moratorium	12.2021	01.2022