PRIOR AUTHORIZATION POLICY

POLICY: Gonadotropin-Releasing Hormone Antagonists – Oriahnn Prior Authorization Policy
- Oriahnn™ (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules – AbbVie)

REVIEW DATE: 04/26/2023

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Oriahnn, an oral gonadotropin-releasing hormone (GnRH) receptor antagonist with added estrogen and progestin therapy, is indicated for the **management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women**.[1] Limitation of Use: Use should be limited to 24 months due to the risk of continued bone loss which may not be reversible.[1]

Disease Overview

Uterine fibroids (leiomyomas) are benign tumors. They are the most frequent gynecologic benign disease.[2] Fibroids can be asymptomatic or cause symptoms; symptoms generally present as abnormal (heavy) uterine bleeding or pelvic pain/pressure. Heavy menstrual bleeding can cause associated problems, such as iron deficiency anemia. The actual prevalence of uterine fibroids is difficult to ascertain since many patients are asymptomatic, but it is estimated that fibroids can be detected in up to 80% of women by 50 years of age.[3]

Guidelines

Oriahnn is addressed in the American College of Obstetrician and Gynecologists guidelines on the management of symptomatic uterine leiomyomas (2021).[4] Medical

treatment options for uterine leiomyomas include agents that address only bleeding symptoms, such as GnRH antagonists, levonorgestrel-releasing intrauterine devices, contraceptive steroids, and tranexamic acid. Agents that reduce both bleeding and leiomyoma size include GnRH agonists and selective progesterone receptor modulators (SPRMs). SPRMs are not approved in the U.S. for the treatment of uterine leiomyomas. An oral GnRH antagonist, such as Oriahnn or Myfembree, can be considered for the treatment of abnormal uterine bleeding related to leiomyomas for up to 2 years. The hormonal add-back therapy is indicated to offset the hypoestrogenic effects of the product.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Oriahnn. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Oriahnn as well as the monitoring required for adverse events and long-term efficacy, approval requires Oriahnn to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Oriahnn™ (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules – AbbVie)
is(are) covered as medically necessary when the following criteria is(are) met for fda-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Uterine Fibroids (Leiomyomas).** Approve for up to 24 months if the patient meets the following criteria (A, B, C, D, E, F, and G):
   Note: Approve for **up to** 24 months. For example, a patient who has already received 6 months of treatment with Oriahnn should be approved for a duration of 18 months.
   A) Patient is ≥ 18 years of age; AND
   B) Patient is PREmenopausal (before menopause); AND
   C) Patient is experiencing heavy menstrual bleeding associated with the uterine fibroids; AND
   D) Uterine fibroids have been confirmed by a pelvic ultrasound, including transvaginal ultrasonography or sonohysterography; hysteroscopy; or magnetic resonance imaging; AND
   E) Patient has tried at least one other therapy for the medical management of heavy menstrual bleeding; AND
   Note: Examples of therapy for the medical management of heavy menstrual bleeding includes: combination estrogen-progestin contraceptives (oral tablets, vaginal ring, transdermal patch), levonorgestrel-releasing intrauterine systems [e.g. Mirena, Liletta], oral progesterone (e.g., medroxyprogesterone acetate), depo-medroxyprogesterone injection, tranexamic acid tablets.

F) Patient has **not** previously received a continuous regimen of 24 months or longer of therapy with Oriahnn or Myfembree; AND

G) The medication is prescribed by or in consultation with an obstetrician-gynecologist or a health care practitioner who specializes in the treatment of women's health.

CONDITIONS NOT COVERED

Oriahnn™ (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules – AbbVie)
is(are) considered experimental, investigational or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Heavy Menstrual Bleeding not associated with Uterine Fibroids.**
   Oriahnn has been shown to be effective in reducing heavy menstrual bleeding only in women with uterine fibroids.[1]

REFERENCES

1. Oriahnn™ co-packaged capsules [prescribing information]. North Chicago, IL: AbbVie; August 2021.
2. Neri M, Melis G, Giancane E, et al. Clinical utility of elagolix as an oral treatment for women with uterine fibroids: A short report on the emerging efficacy data. *Int J Womens Health*. 2019;11:535-546.
3. De La Cruz MS, Buchanan EM. Uterine Fibroids: Diagnosis and Treatment. *Am Fam Physician.* 2017;95(2):100-107.
4. American College of Obstetricians and Gynecologists. ACOG Practice Bulletin. Management of Symptomatic Uterine Leiomyomas. June 2021. Available at: https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2021/06/management-of-symptomatic-uterine-leiomyomas. Accessed on April 20, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual revision	**Uterine Fibroids (Leiomyomas):** Approval duration was updated to "up to" 24 months and a note was added as an example of an appropriate approval duration: Note: Approve for **up to** 24 months. For example, a patient who has already received 6 months of treatment with Oriahnn should be approved for a duration of 18 months. The criterion that patient has not previously received 24 month or longer of therapy with Oriahnn or Myfembree was update to include the wording "a continuous regimen of" 24 months or longer of therapy with Oriahnn or Myfembree.	06/15/2022
Early annual revision	No criteria changes	04/26/2023