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Coverage Policy Number **IP0087**

Oriahnn

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Related Coverage Resources

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.

Overview

This policy supports medical necessity review for elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules (Oriahnn™)

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules (Oriahnn) is considered medically necessary when the following are met:

1. **Uterine Fibroids (Leiomyomas).** Individual meets **ALL** of the following criteria (A, B, C, D, E, F, and G):
    A. Individual is 18 years of age or older
    B. Individual is premenopausal
    C. Individual is experiencing heavy menstrual bleeding associated with the uterine fibroids
    D. Uterine fibroids have been confirmed by imaging

E. Individual has not previously received 24 months or longer of therapy with Oriahnn or Myfembree
F. Documented inadequate response, contraindication, or intolerance to **ONE** of the following (a, b, c, d, or e):
    a. combination oral contraceptives
    b. depo-medroxyprogesterone injection
    c. levonorgestrel-releasing intrauterine systems [e.g. Mirena®, Liletta®]
    d. oral progesterone (for example, medroxyprogesterone acetate)
    e. tranexamic acid tablets

G. Medication is being prescribed by, or in consultation with, an obstetrician-gynecologist or a healthcare practitioner who specializes in the treatment of women's health.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules (Oriahnn) is considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration is up to 12 months.
Reauthorization approval duration is up to 12 months.

Conditions Not Covered

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

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

Background

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.

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.