MEDICAL MUTUAL®

Drug Policy

Policy:	Oriahnn (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules)	Annual Review Date: 09/19/2024 Last Revised Date: 09/19/2024

OVERVIEW

Oriahnn, oral gonadotropin-releasing hormone (GnRH) receptor antagonists with added estrogen and progestin therapy, is indicated for the **management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women**.

A Limitation of Use states that use should be limited to 24 months due to the risk of continued bone loss which may not be reversible.

POLICY STATEMENT

This policy involves the use of Oriahnn. Prior authorization is recommended for pharmacy benefit coverage of Oriahnn. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

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, initial approval requires Oriahnn be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Oriahnn is recommended in those who meet the following criteria:

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], an 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.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 12 months
B) *Extended Approval:* 12 months (Total of 24 months of therapy)

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Oriahnn have not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

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.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:
The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Oriahnn™ (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules), co-packaged for oral use [prescribing information]. North Chicago, IL: AbbVie Inc.; May 2020.
2. Myfembree® (relugolix, estradiol, and norethindrone acetate tablets) [prescribing information]. Brisbane, CA: Myovant Sciences, Inc.; May 2021.
3. 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.
4. De La Cruz MS, Buchanan EM. Uterine Fibroids: Diagnosis and Treatment. *Am Fam Physician.* 2017;95(2):100-107.
5. American College of Obstetricians and Gynecologists. ACOG Practice Bulletin. Alternatives to hysterectomy in the management of leiomyomas. 2008 [reaffirmed 2019]. *Obstet Gynecol.* 2008;112:387-400.
6. Vilos GA, Allaire C, Laberge P, et al. The Management of Uterine Leiomyomas. *J Obstet Gynaecol Can.* 2015;37(2):157-178.