Pharmacy Drug Policy & Procedure

Policy Name:	Oriahnn (elagolix, estradiol, and norethindrone)	Policy #:	2841P

Purpose of the Policy

The purpose of this policy is to define the criteria for coverage of Oriahnn (elagolix, estradiol, and norethindrone) for the treatment of uterine fibroids.

Statement of the Policy

Health Alliance Medical Plans will approve the use of Oriahnn (elagolix, estradiol, and norethindrone) under the Pharmacy benefit if the following criteria are met.

Criteria

1. Coverage Criteria for Uterine Leiomyomas (Fibroids)

1.1 Diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids)
1.2 Age 18 years or older
1.3 Patient is premenopausal
1.4 Documented history of inadequate control of bleeding following a trial of at least 3 months, intolerance, or contraindication to one of the following: estrogen combination (estrogen/progesterone) oral contraceptive, progestins, or tranexamic acid, OR
1.5 Documentation of a previous interventional therapy to reduce bleeding (e.g., uterine-artery embolization, magnetic resonance-guided focused ultrasonography)

2. Exclusion Criteria

2.1 Treatment duration beyond 24 months
2.2 Oriahnn will not be approved if being used in combination with Lupron

3. Approval Period

3.1 Initial Approval: 12 months
3.2 Subsequent Approval: 12 months with documentation of improvement in bleeding associated with uterine leiomyomas (e.g., significant/sustained reduction in menstrual blood loss per cycle, improved quality of life, etc.)

CPT Codes

HCPCS Codes

References

1. Oriahnn (elagolix, estradiol, and norethindrone) [prescribing information]. North Chicago, IL: Abbvie, Inc; June 2023.
2. American College of Obstetricians and Gynecologists' Committee on Practice Bulletins–Gynecology. Management of Symptomatic Uterine Leiomyomas: ACOG Practice Bulletin, Number 228. Obstet Gynecol. 2021 Jun 1;137(6):e100-e115.
3. Schlaff WD, Ackerman RT, Al-Hendy A, et al. Elagolix for heavy menstrual bleeding in women with uterine fibroids. N Engl J Med. 2020;382(4):328-340.

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DISCLAIMER
This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.