Policy Name:	Myfembree (Relugolix, Estradiol, and Norethindrone)	Policy #:	3052P

Purpose of the Policy

The purpose of this policy is to define the criteria for coverage of Myfembree.

Statement of the Policy

Health Alliance Medical Plans will approve the use of Myfembree under the Pharmacy benefit if the following criteria are met.

Criteria

1. Coverage Criteria for Endometriosis

1.1 Diagnosis of moderate to severe pain associated with endometriosis
1.2 Age 18 years or older
1.3 Patient is premenopausal
1.4 Ordered by or in consultation with an obstetrician-gynecologist
1.5 Documented failure, intolerance, or contraindication to a 3-month trial of NSAIDs and contraceptives

2. Coverage Criteria for Uterine Leiomyomas (Fibroids)

2.1 Diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids)
2.2 Age 18 years or older
2.3 Patient is premenopausal
2.4 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
2.5 Documentation of a previous interventional therapy to reduce bleeding (e.g., uterine-artery embolization)

3. Exclusion Criteria

3.1 Treatment duration beyond 24 months
3.2 Myfembree will not be approved if being used in combination with Lupron, Orilissa, or Oriahnn

4. Approval Period

4.1 Initial Approval: 12 months
4.2 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. Myfembree (relugolix, estradiol, and norethindrone) [prescribing information]. Brisbane, CA: Myovant Sciences Inc; February 2023.
2. Al-Hendy A, Lukes AS, Poindexter AN 3rd, et al. Treatment of uterine fibroid symptoms with relugolix combination therapy. N Engl J Med. 2021;384(7):630-642.
3. Giudice LC, As-Sanie S, Arjona Ferreira JC, et al. Once daily oral relugolix combination therapy versus placebo in patients with endometriosis-associated pain: two replicate phase 3, randomised, double-blind, studies (SPIRIT 1 and 2). Lancet. 2022;399(10343):2267-2279.
4. Saridogan E, Tomassetti C, van Hanegem N, et al. ESHRE guideline: management of women with endometriosis. Hum Reprod Open. 2022 Feb 26;2022(2):hoac009.
5. 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.

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