CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Myfembree (relugolix, estradiol, and norethindrone acetate)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Myfembree is a fixed-dose combination of relugolix 40 mg, estradiol 1 mg, and norethindrone acetate 0.5 mg indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women. Relugolix is a GnRH receptor antagonist. The addition of the estradiol component may reduce the extent of bone loss from the decreased estrogen concentration resulting from relugolix. The purpose of the norethindrone component is to protect from potential adverse effects of unopposed estrogen. The use of Myfembree must not exceed 24 months due to the risk of bone loss. Myfembree was approved in 2021 and will directly compete with Oriahnn (elagolix, estradiol, norethindrone) which is also an oral GnRH antagonist. Although a head-to-head trial has not been done, there appears to be limited clinical differentiation between the two products. An advantage of Myfembree is that it is taken once daily rather than twice daily.

Myfembree (relugolix, estradiol, and norethindrone acetate) will be considered for coverage when the following criteria are met:

Uterine Fibroids

For **initial** authorization:

1. Member is a premenopausal female at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with an OB/GYN; AND
3. Member has a documented diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids); AND
4. Member has had no less than a 90-day trial and failure of at least one of the following: Oral contraceptive, levonorgestrel-releasing intrauterine device (IUD), or tranexamic acid; AND
5. Member does not have ANY of the following:
   a) Pregnancy or plan to become pregnant during treatment
   b) Osteoporosis
   c) History or high risk of thrombotic or thromboembolic disorders
   d) Current or history of breast cancer or other hormone-sensitive malignancies.
6. **Dosage allowed/Quantity limit:** 1 tablet once daily (28 tablets per 28 days)

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes must show reduction in menstrual blood loss volume and/or an improvement in hemoglobin level and/or significantly reduced fibroid-related pain.

If all the above requirements are met, the medication will be approved for an additional 12 months. **TOTAL DURATION OF THERAPY NOT TO EXCEED 24 MONTHS**.

CareSource considers Myfembree (relugolix, estradiol, and norethindrone acetate) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
08/10/2021	New policy for Myfembree created.

References:

1. Myfembree [package insert]. Brisbane, CA: Myovant Sciences, Inc; 2021.
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. doi:10.1056/NEJMoa2008283
3. De La Cruz MS, Buchanan EM. Uterine Fibroids: Diagnosis and Treatment. *Am Fam Physician*. 2017;95(2):100-107.
4. Stewart, EA. Uterine fibroids (leiomyomas): Treatment overview. *UpToDate*. Updated August 6, 2021. Accessed August 12, 2021.
5. Vilos GA, Allaire C, Laberge PY, Leyland N; SPECIAL CONTRIBUTORS. The management of uterine leiomyomas. *J Obstet Gynaecol Can*. 2015;37(2):157-178. doi:10.1016/S1701-2163(15)30338-8

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