PHARMACY POLICY STATEMENT
North Carolina 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 and endometriosis. 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 (relugolix, estradiol, and norethindrone acetate) will be considered for coverage when the following criteria are met:

Uterine Fibroids

For initial authorization:

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.
2. Duration of treatment has not exceeded 24 months.

If all the above requirements are met , the medication will be approved for an additional 12 months. Reauthorization will not be allowed after 2 4 months of therapy.

Endometriosis

For initial authorization:

1. Member is premenopausal and 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a gynecologist; AND
3. Member is having moderate to severe painful symptoms (e.g., pelvic pain, dysmenorrhea, etc.) associated with endometriosis (documentation required); AND
4. Member has tried and failed to control symptoms after trials with both of the following, unless not tolerated or contraindicated:
   a) 30 days of an NSAID;
   b) 3 months of a hormonal contraceptive; 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 1 2 months.

For reauthorization :