Relugolix/ estradiol/ norethindrone (Myfembree)

Coverage Criteria for Heavy Bleeding Associated with Uterine Leiomyomas:

1. The patient will use Myfembree for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women, AND
2. The patient is 18 years of age and older, AND
3. Prescribed by or in consultation with OB/GYN, AND
4. The patient has tried and failed or has a contraindication to at least two of the following:
   a. Preferred (oral or vaginal) contraceptives (two contraceptives is an acceptable trial/failure);
   b. Levonorgestrel intra-uterine device (IUD);
   c. Oral tranexamic acid; AND
5. Surgical intervention has been discussed and is not an appropriate treatment option or patient declines; AND
6. Prescribed within the FDA approved regimen

Coverage Duration:
6 months initial, 18 months renewal

Renewal Criteria:
1. Physician attestation of improvement of heavy menstrual bleeding, AND
2. Prescribed within the FDA approved regimen

Coverage Criteria for Pain Associated with Endometriosis:

1. Prescribed by or in consultation with a prescriber specializing in obstetrics and gynecology. Exceptions will be made on a case by case basis for patients that have geographical or other restraints limiting access to a specialist; and,
2. Patient has a diagnosis of endometriosis that is causing moderate to severe pain; and,
3. Patient has tried and failed or has a contraindication to all of the following;
   a. Prescription strength non-steroidal anti-inflammatory therapy (NSAID); and,
   b. Continuous oral contraceptive therapy or high dose progesterone therapy (equivalent to medroxyprogesterone 10-20 mg); and,
   c. Attestation that a surgical intervention has been discussed and is not an appropriate treatment option or patient declines procedure; and,
   d. Orilissa; and,
4. Patient does not have a contraindication to Myfembree therapy. Contraindications include pregnancy, osteoporosis and severe hepatic impairment (Child-Pugh class C); and,
5. Myfembree will NOT be used concurrently (at the same time) with another GnRH modulating agent (such as Orilissa, Lupron Depot, Synarel); and,
6. Prescribed within FDA approved dosing regimen, including appropriate limits on total duration of therapy

P&T Date: 7/12/2021, 11/14/2022
Effective Date: 10/1/2021, 1/1/2023

Coverage Duration:
Initial authorization will be provided for 6 months. Reauthorization will be provided for 18 months. Please note: There is a maximum lifetime duration of 24 months with Myfembree, as outlined in the medication's prescribing information. Total therapy durations exceeding 24 months will not be approved.

Renewal Criteria:
The patient has had a positive response to therapy (which includes a decrease in pain since starting on the medication).