Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	October 29, 2021 April 13, 2023

MYFEMBREE® (relugolix, estradiol, and norethindrone acetate) tablets

LENGTH OF AUTHORIZATION: SIX MONTHS

INITIAL REVIEW CRITERIA:

Uterine leiomyomas (fibroids) with heavy menstrual bleeding

- Patient is ≥ 18 years of age; **AND**
- Patient has a confirmed diagnosis of uterine leiomyomas (fibroids) with heavy menstrual bleeding; **AND**
- Prescribed or in consultation with a specialist in gynecology or reproductive health; **AND**
- Patient is premenopausal; **AND**
- Patient has failed (or has contraindication to) adequate trial of the following therapy:
  - Combination hormonal contraceptives, and/or progestin containing oral or depot (e.g. norethindrone)

Moderate to severe pain associated with endometriosis

- Patient is ≥ 18 years of age; **AND**
- Patient has a confirmed diagnosis of moderate to severe pain associated with endometriosis **AND**
- Prescribed or in consultation with a specialist in gynecology or reproductive health; **AND**
- Patient is premenopausal; **AND**
- Documented trial and failure of analgesics; **AND**
- Patient has failed (or has contraindication to) adequate trial of the following therapy:
  - Combination hormonal contraceptives, and/or progestin containing oral or depot (e.g. norethindrone)

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as a fixed-dose combination tablet containing relugolix 40 mg, estradiol 1 mg and norethindrone acetate 0.5 mg.
- Treatment should be limited to 24 months due to the risk of continued bone loss, which may not be reversible.