

STATE OF WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES BUREAU FOR MEDICAL SERVICES



Office of Pharmacy Services Prior Authorization Criteria Myfembree® (Relugolix, Estradiol, and Norethindrone acetate) Effective 1/1/2023

Prior Authorization Request Form

Myfembree is a combination of relugolix, a gonadotropin-releasing hormone (GnRH) receptor antagonist, estradiol, an estrogen, and norethindrone acetate, a progestin, indicated in premenopausal women for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) and management of moderate to severe pain associated with endometriosis.

CRITERIA FOR APPROVAL:

- Patient must be a premenopausal woman diagnosed with heavy menstrual bleeding associated with uterine leiomyomas (fibroids) or diagnosed with moderate to severe pain associated with endometriosis; AND
- 2. Patient must be within the age range as recommended by the FDA label; AND
- 3. Patient must not be pregnant; AND
- 4. Patient must not be diagnosed with osteoporosis; AND
- For heavy menstrual bleeding associate with uterine leiomyomas (fibroids): The patient has failed a 90-day trial with one agent from <u>ONE</u> the following categories (unless contraindicated):
 - a. Combination Estrogen/Progestin contraceptives
 - b. Progestin therapy (oral, transdermal, vaginal ring, IUD, or injections)
 - c. Tranexamic acid
- 6. For moderate to severe pain associated with endometriosis:
 - a. The patient has failed to achieve significant symptomatic relief with NSAID therapy (please provide documentation); **AND**
 - Patient has failed a 90-day trial with one agent from ONE of the following categories (unless contraindicated):
 - 1. Extended-cycle combined oral contraceptive OR progestin therapy
 - 2. GnRH agonist

Approval Duration: Initial approval will be for 90 days.



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Criteria for reauthorization:

1. Demonstrate continued documented compliance; AND

 Patient has experienced clinically significant improvement in symptoms as compared to that seen using previous therapy.

Maximum length of therapy is limited to 24 months due to the risk of continued bone loss, which may not be reversible.

References:

- 1.) Myfembree Package Insert
- 2.) Lexi-Comp Clinical Application 11/2021, 11/2022
- 3.) UpToDate Clinical monograph: Uterine fibroids (leiomyomas): Treatment overview reviewed 11/2021, 11/2022