

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:

- 1. 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 ONE 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:
 - The patient has failed to achieve significant symptomatic relief with NSAID therapy (please provide documentation); AND
 - b. 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.

DUR Board Approval: 11/17/2021

Updated: 11/16/2022



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Criteria for reauthorization:

- 1. Demonstrate continued documented compliance; AND
- 2. Patient has experienced clinically significant improvement in symptoms as compared to that seen using previous therapy.

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

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

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