Commercial/Healthcare Exchange PA Criteria

Effective: September 14, 2021

Prior Authorization: Myfembree

Products Affected: Myfembree (relugolix, estradiol, and norethindrone acetate) tablets

Medication Description: Relugolix is a non-peptide gonadotropin releasing hormone (GnRH) receptor antagonist that competitively binds to pituitary GnRH receptors, thereby reducing the release of luteinizing hormone (LH) and follicle-stimulating hormone (FSH), leading to decreased serum concentrations of the ovarian sex hormones estradiol and progesterone and reduced bleeding associated with uterine fibroids. Estradiol acts by binding to nuclear receptors that are expressed in estrogen responsive tissues. Progestins such as norethindrone act by binding to nuclear receptors that are expressed in progesterone responsive tissues. As a component of relugolix/estradiol/norethindrone, the addition of exogenous estradiol may reduce the increase in bone resorption and resultant bone loss that can occur due to a decrease in circulating estrogen concentrations from relugolix alone, and norethindrone may protect the uterus from the potential adverse endometrial effects of unopposed estrogen.

Covered Uses:

1. Menorrhagia - Uterine leiomyoma, In premenopausal women
2. Moderate to Severe Pain associated with Endometriosis

Exclusion Criteria: Myfembree is contraindicated in women:

- With a high risk of arterial, venous thrombotic, or thromboembolic disorders. Examples include women over 35 years of age who smoke, and women who are known to have:
    - current or history of deep vein thrombosis or pulmonary embolism
    - vascular disease (e.g., cerebrovascular disease, coronary artery disease, peripheral vascular disease)
    - thrombogenic valvular or thrombogenic rhythm diseases of the heart (for example, subacute bacterial endocarditis with valvular disease, or atrial fibrillation)
    - inherited or acquired hypercoagulopathies
    - uncontrolled hypertension
    - headaches with focal neurological symptoms or migraine headaches with aura if over 35 years of age
- Who are pregnant.
- With known osteoporosis.
- With current or history of breast cancer or other hormone-sensitive malignancies, and with increased risk for hormone-sensitive malignancies.
- With known hepatic impairment or disease.
- With undiagnosed abnormal uterine bleeding.
- With known anaphylactic reaction, angioedema, or hypersensitivity to Myfembree or any of its components.

Required Medical Information:

1. Diagnosis
2. Previous medications tried and failed

3. Medical history

Age Restrictions: 18 years of age and older

Prescriber Restrictions: Prescribed by, or in consultation with, an obstetrician-gynecologist, or a health care practitioner who specializes in the treatment of women's health.

Coverage Duration: 24 months;
Use of Myfembree should be limited to 24 months due to the risk of continued bone loss which may not be reversible.

Other Criteria:
Approval Criteria
1. Menorrhagia - Uterine leiomyoma, In premenopausal women
Patient must meet all the below criteria:

A. Patient is a Premenopausal woman (before menopause); **AND**
B. Patient is experiencing heavy menstrual bleeding associated with the uterine fibroids; **AND**
C. Patient has tried at least one other therapy for the medical management of heavy menstrual bleeding.
Note: Examples of therapy for the medical management of heavy menstrual bleeding: combination estrogen-progestin contraceptives (oral tablets, vaginal ring, transdermal patch), levonorgestrel-releasing intrauterine systems (e.g., Mirena®, Liletta®), an oral progesterone (e.g., medroxyprogesterone acetate), depo-medroxyprogesterone injection, tranexamic acid tablets; **AND**
D. Patient has NOT previously received 24 months or longer of therapy with Oriahnn or Myfembree

2. Moderate to Severe Pain Associated with Endometriosis
A. Patient is PREmenopausal (before menopause); **AND**
B. Patient has previously used one of the following (i or ii):
Note: An exception to this requirement can be made if the patient has previously used a gonadotropin-releasing hormone agonist (e.g., Lupron Depot) or antagonist (e.g., Orilissa).
i. A contraceptive (e.g., combination oral contraceptives, levnorgestrel-releasing intrauterine systems [e.g., Mirena, Liletta]), a depo-medroxyprogesterone injection), unless contraindicated; **OR**
ii. An oral progesterone (e.g., norethindrone tablets), unless contraindicated.

References:

1. Myfembree® [package insert]. Brisbane, CA. Myovant Sciences, Inc. Updated June 7, 2021. Accessed August 9, 2021.
2. Myfembree®. IBM Micromedex® [database online]. Greenwood Village, CO. Truven Health Analytics. Available at: https://www.micromedexsolutions.com. Updated June 28, 2021. Accessed August 6, 2021.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	9/14/2021

2	Update Policy	Added Moderate to Severe Pain associated with Endometriosis to Covered Uses and Other Criteria	Covered Uses, Other Criteria	1/19/2023