CONSIDERATIONS FOR COMPLETING MEDICAL NECESSITY OR MEDICAL EXCEPTION REQUESTS

This resource is intended as educational support to assist providers who would like to complete a medical necessity or exception request. The provider has the responsibility to ensure correct policies are followed. Providers must ensure they accurately complete and submit necessary information to payers. Use of these tips or the checklist does not guarantee that the health plan will provide reimbursement for medication, nor are they intended to be a substitute for, or influence on, providers' independent medical judgment.

Information on Completing Medical Necessity and Medical Exception Requests

- When patients are prescribed Myfembree, it is possible that their health plan may require utilization management (prior authorization or step therapy) before approval or not have Myfembree on formulary/covered. In such cases, a request for medical necessity or medical exception can be submitted, respectively

Please note: **This template is for reference only, and it is the prescriber's responsibility to complete the letter based on their independent medical judgment**

- A letter detailing the patient's case and reasoning behind treatment selection should be included. A sample letter is available through your representative or at https://www.myfembreehcp.com/files/sample-letter-of-medical-exception-and-necessity.docx
- Health plans may have their own criteria for submitting a medical necessity or medical exception request and may require a unique form that has to be filled out along with the request
- It is important to ensure that correct ID numbers are provided, such as your provider ID number, the patient's insurance ID number, and the correct ICD-10-CM diagnosis code for the patient's condition
- Your office should follow-up with the health plan to verify that the medical necessity or exception submission was successfully received and to confirm that certain time period guidelines have been met for successful submission. Health plans generally have guidelines for expected response times, and many states have regulations about the amount of time that a health plan may take to respond
- Information that supports the diagnosis and treatment, such as lab results, may be included along with any other supporting documentation as required by the payer (eg, Myfembree package insert)
- Some health plans may require that a diagnosis be provided by an appropriate specialist
- The list below is meant as a resource to help providers complete a medical necessity or medical exception request and is not exhaustive. It is important to be familiar with all of a health plan's medical necessity or exception requirements

Submission Checklist

- ☐ Verification of health plan's medical necessity or medical exception submission criteria and indication of specialist type (eg, OB/GYN)
- ☐ Completed medical necessity or medical exception form from health plan (if applicable)
- ☐ Letter of medical necessity or medical exception
- ☐ Confirmation of previous treatment failures (if applicable)
- ☐ Correct contact information for the office
- ☐ Information that supports the diagnosis and treatment (eg, lab results, blood tests, etc)
- ☐ Supporting documentation as required by the payer (eg, signed prescription form, Myfembree package insert)
- ☐ Photocopy of the patient's insurance card
- ☐ Call to health plan to verify successful submission
- ☐ Call to health plan to check status of submission/response

Ask your representative about sample letters

Sample Letter of Coverage Denial Appeal

Sample Letter of Medical Necessity or Exception

ICD-10-CM=*International Classification of Diseases, Tenth Revision, Clinical Modification*.

INDICATIONS

Myfembree is indicated in premenopausal women for the management of:

- Heavy menstrual bleeding associated with uterine leiomyomas (fibroids)
- Moderate to severe pain associated with endometriosis

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

IMPORTANT SAFETY INFORMATION

BOXED WARNING: THROMBOEMBOLIC DISORDERS AND VASCULAR EVENTS

- **Estrogen and progestin combinations, including Myfembree, increase the risk of thrombotic or thromboembolic disorders including pulmonary embolism, deep vein thrombosis, stroke and myocardial infarction, especially in women at increased risk for these events.**
- **Myfembree is contraindicated in women with current or a history of thrombotic or thromboembolic disorders and those at increased risk for these events, including women >35 years of age who smoke or with uncontrolled hypertension.**

Please see next page for additional Important Safety Information and full Prescribing Information, including BOXED WARNING.

Myfembree®
(relugolix, estradiol, and norethindrone acetate) tablets
40 mg, 1 mg, 0.5 mg

IMPORTANT SAFETY INFORMATION (cont'd)

CONTRAINDICATIONS

Myfembree is contraindicated in women with: high risk of arterial, venous thrombotic, or thromboembolic disorder; pregnancy; known osteoporosis; current or history of breast- or other hormone-sensitive cancers; known hepatic impairment or disease; undiagnosed abnormal uterine bleeding; known hypersensitivity to components of Myfembree.

WARNINGS AND PRECAUTIONS

Thromboembolic Disorders: Discontinue immediately if an arterial or venous thrombotic, cardiovascular, or cerebrovascular event occurs or is suspected; or if there is sudden unexplained partial or complete loss of vision, proptosis, diplopia, papilledema or retinal vascular lesions and evaluate for retinal vein thrombosis. Discontinue ≥4 to 6 weeks before surgery associated with an increased risk of thromboembolism or during prolonged immobilization.

Bone Loss: Myfembree may decrease bone mineral density (BMD) in some patients, which may be greater with longer use and may not be completely reversible. Consider the benefits and risks in patients with a history of low trauma fracture or risk factors for osteoporosis or bone loss. Baseline dual-energy X-ray absorptiometry (DXA) is recommended in all women. During treatment, DXA is recommended periodically for heavy menstrual bleeding due to uterine fibroids and annually for moderate to severe endometriosis pain.

Hormone-Sensitive Malignancies: Discontinue Myfembree if a hormone-sensitive malignancy is diagnosed. Breast exams and mammography are recommended. Use of estrogen alone or estrogen plus progestin has resulted in abnormal mammograms requiring further evaluation.

Suicidal Ideation and Mood Disorders (Including Depression): Evaluate patients with a history of suicidal ideation, depression, and mood disorders before starting treatment. Monitor for these symptoms including shortly after initiating treatment. Advise patients to seek medical care for new or worsening depression, anxiety, other mood changes, or suicidal ideation and behavior. Gonadotropin-releasing hormone receptor antagonists, including Myfembree, have been associated with mood disorders (including depression) and suicidal ideation.

Hepatic Impairment and Transaminase Elevations: Due to poor metabolism of steroid hormones, instruct these patients to promptly seek medical care for symptoms/signs of liver injury, e.g., jaundice or right upper abdominal pain. Acute liver test abnormalities may require discontinuing Myfembree until tests return to normal and Myfembree causation is excluded.

Gallbladder Disease or History of Cholestatic Jaundice: Discontinue Myfembree if signs/symptoms of gallbladder disease or jaundice occur. Studies among estrogen users suggest a small increased relative risk of developing gallbladder disease.

Elevated Blood Pressure: Do not use in women with uncontrolled hypertension. For women with well-controlled hypertension, continue to monitor blood pressure and stop Myfembree if blood pressure rises significantly.

Change in Menstrual Bleeding Pattern and Reduced Ability to Recognize Pregnancy: Advise women to use non-hormonal contraception during and for one week after discontinuing Myfembree. Avoid use with hormonal contraceptives. Myfembree may delay recognition of pregnancy because it alters menstrual bleeding. Test for pregnancy if suspected and discontinue Myfembree if confirmed.

Risk of Early Pregnancy Loss: Myfembree can cause early pregnancy loss. Exclude pregnancy before initiating and advise women to use non-hormonal contraception.

Uterine Fibroid Prolapse or Expulsion: Advise women with known or suspected submucosal uterine fibroids about the risk of uterine fibroid prolapse or expulsion and instruct them to contact their physician if severe bleeding/cramping occurs.

Alopecia: Alopecia, hair loss, and hair thinning were reported in phase 3 trials in women with heavy menstrual bleeding associated with uterine fibroids with Myfembree. Whether hair loss is reversible is unknown.

Effects on Carbohydrate and Lipid Metabolism: More frequent monitoring in women with prediabetes and diabetes may be necessary. Myfembree may decrease glucose tolerance and increase blood glucose concentrations. Monitor lipid levels and consider discontinuing if hypercholesterolemia or hypertriglyceridemia worsens. In women with pre-existing hypertriglyceridemia, estrogen therapy may increase triglycerides levels leading to pancreatitis. Myfembree is associated with increases in total cholesterol and LDL-C.

Effect on Other Laboratory Results: Patients with hypothyroidism and hypoadrenalism may require higher doses of thyroid hormone or cortisol replacement therapy. Combined estrogen and progestin may raise serum concentrations of binding proteins, which may reduce free thyroid or corticosteroid hormone levels. Estrogen and progestin may also affect the levels of sex hormone-binding globulin and coagulation factors.

Hypersensitivity Reactions: Immediately discontinue Myfembree if a hypersensitivity reaction occurs.

ADVERSE REACTIONS: Most common adverse reactions (incidence ≥3% and greater than placebo) were:

- Heavy menstrual bleeding associated with uterine fibroids: vasomotor symptoms, abnormal uterine bleeding, alopecia, and decreased libido.
- Moderate to severe pain associated with endometriosis: headache, vasomotor symptoms, mood disorders, abnormal uterine bleeding, nausea, toothache, back pain, decreased sexual desire and arousal, arthralgia, fatigue, and dizziness.

These are not all the possible side effects.

Please see Important Safety Information throughout and full Prescribing Information, including BOXED WARNING.

Sumitomo Pharma

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