Myfembree® (relugolix, estradiol, and norethindrone acetate)

Prior Authorization (PA) Considerations

This resource is provided to support patient access to Myfembree as prescribed. It is for informational purposes only and is not intended to provide recommendations. It is not a comprehensive description of potential payer access requirements for Myfembree. The prescriber is solely responsible for determining coverage and reimbursement requirements and submitting the necessary information to payers. Use of this resource does not guarantee that the health plan will provide coverage or reimbursement for Myfembree. Nothing within this resource is intended to be a substitute for, or influence on, prescribers' independent medical judgment.

For eligible commercially insured patients, approximately

94% of women are covered for Myfembree nationwide[1,2*]

when prescribed for heavy menstrual bleeding due to uterine fibroids or for moderate to severe pain due to endometriosis

Myfembree formulary coverage in your area

Scan the QR code to access the Formulary Lookup Tool and obtain the coverage information that matters to you.

Understanding PA requirements after a patient has been prescribed Myfembree

When you prescribe Myfembree for FDA-approved indications, write the prescription the way you normally do. Your patient's health plan may require a PA before coverage is approved for Myfembree. In such cases, the patient's health plan has certain requirements that must be met before the medication is covered. Inside this resource, healthcare providers (HCPs) can find information regarding:

Considerations for submitting a PA | **Common PA criteria for Myfembree** | **Example ICD-10-CM diagnostic category codes**

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 combination products, 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.**

FDA=US Food and Drug Administration; ICD-10-CM=*International Classification of Diseases, Tenth Revision, Clinical Modification*.

*This coverage information is provided for informational purposes only; individual plans vary, and this may not include all plans. Sumitomo Pharma America and Pfizer make no representation or guarantee concerning coverage or reimbursement; please check with individual payers for plan-specific coverage and reimbursement information and requirements. Nothing herein may be construed as an endorsement, approval, recommendation, representation, or warranty of any kind by any plan or insurer referenced. This information is subject to change without notice.

Data on file. Formulary data are provided by MMIT, LLC, as of September 2023.

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

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40 mg, 1 mg, 0.5 mg

Prescriber considerations for submitting a PA

Confirm what information or form is required

- PA criteria may vary by health plan, and many plans will have specific PA request forms available on their website that enable provision of their required information
- Some plans may require patient medical records with appropriate chart notes and additional clinical tests

Complete all sections of the PA form along with any other required supplemental documentation required by the health plan

Submit the PA request and include all required clinical documentation

- When a PA is successfully submitted, a copy of the form should be kept on file

Follow up with the health plan on the status of the PA request

PA=prior authorization.

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.

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Examples of common PA criteria questions*

The following pertains to indications for premenopausal women with heavy menstrual bleeding due to uterine fibroids and moderate to severe pain due to endometriosis.

General Patient History Questions

- Is the patient 18 years or older?
- Is the patient a premenopausal woman?
- Does the patient have a history of trial, failure, contraindication, or intolerance of hormonal contraceptives?
- Is the patient pregnant?
- Has the patient previously received 24 months or longer of therapy with a GnRH antagonist?
- Does the patient have known liver impairment?
- Does the patient have osteoporosis?
- Is Myfembree being prescribed by or in consultation with an obstetrician-gynecologist or a healthcare practitioner who specializes in the treatment of women's health?

Indication-Specific Questions (Heavy Menstrual Bleeding Associated With Uterine Leiomyomas [Fibroids])

- Does the patient have heavy menstrual bleeding associated with uterine fibroids?
- Does the patient have undiagnosed abnormal uterine bleeding?

Indication-Specific Questions (Moderate to Severe Pain Associated With Endometriosis)

- Does the patient have moderate to severe pain associated with endometriosis?
- Does the patient have a history of trial, failure, contraindication, or intolerance to pain relievers (ie, naproxen, ibuprofen, meloxicam)?

GnRH=gonadotropin-releasing hormone; PA=prior authorization.

*These examples are provided for informational purposes only and are not a complete list of criteria that a health plan may consider when making coverage decisions. It is the prescriber's responsibility to verify payer-specific PA criteria to ensure accuracy/completeness, as prior authorization requirements may change over time.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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: In women with well-controlled hypertension, monitor blood pressure and stop Myfembree if it 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.

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Example ICD-10-CM diagnostic category codes related to uterine fibroids and heavy menstrual bleeding (HMB)*

INDICATIONS

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- 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.

Common ICD-10-CM codes related to uterine fibroids and heavy menstrual bleeding are listed below. For an up-to-date list including additional applicable codes, please refer to an ICD-10-CM resource.

Uterine Fibroid and Uterine Leiomyoma[3]	
ICD-10-CM	**Condition**
D25	Leiomyoma of uterus
D25.0	Submucous leiomyoma of uterus
D25.1	Intramural leiomyoma of uterus
D25.2	Subserosal leiomyoma of uterus
D25.9	Leiomyoma of uterus, unspecified
Heavy Menstrual Bleeding[3]	
ICD-10-CM	**Condition**
N92.0	Excessive and frequent menstruation with regular cycle
N92.1	Excessive and frequent menstruation with irregular cycle
N92.4	Excessive bleeding in the premenopausal period
N92.5	Other specified irregular menstruation
N92.6	Irregular menstruation, unspecified
N93.8	Other specified abnormal uterine and vaginal bleeding
N93.9	Abnormal uterine and vaginal bleeding, unspecified

FDA=US Food and Drug Administration; ICD-10-CM=*International Classification of Diseases, Tenth Revision, Clinical Modification*.

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IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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.

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Example ICD-10-CM diagnostic category codes related to endometriosis*

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Common ICD-10-CM codes related to endometriosis are listed below. For an up-to-date list including additional applicable codes, please refer to an ICD-10-CM resource.

Endometriosis[3]

ICD-10-CM	Condition
N80.0	Endometriosis of uterus
N80.1	Endometriosis of ovary
N80.2	Endometriosis of fallopian tube
N80.3	Endometriosis of pelvic peritoneum
N80.4	Endometriosis of rectovaginal septum and vagina
N80.5	Endometriosis of intestine
N80.6	Endometriosis in cutaneous scar
N80.8	Other endometriosis
N80.9	Endometriosis, unspecified

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IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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.

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Coverage and PA assistance options

The Myfembree® Support Program can help you understand coverage for your Myfembree patients

Call the Myfembree Support Program at 1-833-MYFEMBREE (1-833-693-3627), 8 AM–8 PM ET, Monday–Friday

PA determinations available faster* through

covermymeds®

covermymeds.com

- Submit requests for any medication and all plans
- Renew previously submitted requests
- Receive faster PA determinations*
- Use at no cost

Live support:

Via chat box at **CoverMyMeds.com**

By phone at 1-866-452-5017, Monday–Friday, 8:00 AM–11:00 PM ET; Saturday, 8:00 AM–6:00 PM ET

Get started now

PA=prior authorization.

*Online PA submissions are faster compared to phone and fax methods.

IMPORTANT SAFETY INFORMATION (cont'd)

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.

LACTATION: Advise women not to breastfeed while taking Myfembree.

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References: 1. Data on file. Sumitomo Pharma America. 2022. **2.** Formulary data are provided by MMIT, LLC, as of September 2023. **3.** 2023 ICD-10-CM. Centers for Medicare and Medicaid Services. Accessed July 17, 2023. https://www.cms.gov/medicare/coding-billing/icd-10-codes/2023-icd-10-cm

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