

CONSIDERATIONS FOR APPEALING A COVERAGE DENIAL

This flashcard provides educational information for healthcare providers (HCPs) and office staff following a denied prior authorization (PA) request or rejected pharmacy claim. HCPs are responsible for following all health plan requirements for coverage and for submitting appeals. Following the steps within this guide does not guarantee that health plans will cover Myfembree® (relugolix, estradiol, and norethindrone acetate) or reimburse part or all of its cost. This guidance is not intended to substitute or influence an HCP's independent medical judgment.

These steps and resources may help you navigate the appeals process if a patient prescribed Myfembree receives a coverage denial:

Find out why the PA was denied:

1

- Check the explanation of benefits or call the health plan directly to confirm the reason for denial
- Act promptly as health plans often impose time limits on appeals
- If the denial is due to a non-clinical reason, a reconsideration may be requested without filing an appeal
- If the PA was denied for a clinical reason, follow the health plan's instructions on how to submit an appeal



covermymeds®

CoverMyMeds provides an automated solution to submit PA and appeal requests for Myfembree, including ways to attach supporting documentation. Call 1-866-452-5017 or visit www.covermymeds.health to get started.

If needed, draft a patient-specific letter of appeal:

2

- Check the health plan's coverage criteria for Myfembree
- Ensure the appeal addresses the specific reason(s) why the health plan denied coverage



A Sample Letter of Coverage Denial Appeal

for Myfembree is available through your representative or at <https://www.myfembreehcp.com/files/sample-letter-of-coverage-denial-appeal.docx>.

The template letter can be customized with the patient's clinical information, copied onto office letterhead, signed by the treating HCP, and submitted to the health plan.

Include supporting documentation to help explain why Myfembree is medically necessary for the patient:

3

- Medical chart notes or test results
- Prescribing Information for Myfembree
- Myfembree's FDA approval letter
- Peer-reviewed studies



Documentation requirements for Myfembree may include:

- Diagnosis consistent with labeled indication
- List of failed therapies (eg, NSAIDs, hormonal birth control, etc), including dates and reasons for discontinuation
- Contraindications to other therapies
- Lab work, imaging studies, or other diagnostic information
- Prior surgeries or procedures with dates and outcomes
- Prescription by or in consultation with a specialist

Submit the appeal and follow up to ensure receipt:

4

- Respond promptly to any communication from the health plan
- Check regularly until the health plan makes a decision



If the appeal is denied, HCPs or their office staff may request a peer-to-peer or third-party review.

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

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 $\geq 3\%$ 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.



MYFEMBREE® and its logo are registered trademarks of Sumitomo Pharma Co., Ltd., used under license.

All other trademarks are the property of their respective owners.

◆ is a trademark of Sumitomo Pharma Co., Ltd., used under license.

SUMITOMO PHARMA is a trademark of Sumitomo Pharma Co., Ltd., used under license.

SUMITOMO is a registered trademark of Sumitomo Chemical Co., Ltd., used under license.

Sumitomo Pharma America, Inc. is a U.S. subsidiary of Sumitomo Pharma Co. Ltd.

©2026 Sumitomo Pharma America, Inc. All rights reserved. MYF-US-0270-25 02/26



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