PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

MYFEMBREE
(relugolix/estradiol/norethindrone acetate)

Status: CVS Caremark® Criteria
Type: Initial Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Heavy Menstrual Bleeding Associated with Uterine Leiomyomas
Myfembree is indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women.

Moderate to Severe Pain Associated with Endometriosis
Myfembree is indicated for the management of moderate to severe pain associated with endometriosis in premenopausal women.

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

COVERAGE CRITERIA

Heavy Menstrual Bleeding Associated with Uterine Leiomyomas (Fibroids)
Authorization may be granted when the requested drug is being prescribed for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) when ALL the following criteria is met:

- The patient is premenopausal
- If the patient has previously received treatment with an elagolix-containing product (e.g., Oriahnn, Orilissa) or a relugolix-containing product (e.g., Myfembree), the patient has not already received ANY of the following: greater than or equal to 24 cumulative months of treatment with elagolix-containing products (e.g., Oriahnn, Orilissa) and/or relugolix-containing products (e.g., Myfembree), greater than or equal to 6 months of treatment with Orilissa 200 mg twice daily

Moderate to Severe Pain Associated with Endometriosis
Authorization may be granted when the requested drug is being prescribed for the management of moderate to severe pain associated with endometriosis when ALL the following criteria are met:

- The patient is premenopausal
- The patient has not received the maximum recommended treatment course of 12 months of Lupron Depot or Lupaneta Pack OR 6 months of Synarel or Zoladex
- If the patient has previously received treatment with an elagolix-containing product (e.g., Oriahnn, Orilissa) or a relugolix-containing product (e.g., Myfembree), the patient has not already received ANY of the following: greater than or equal to 24 cumulative months of treatment with elagolix-containing products (e.g., Oriahnn, Orilissa) and/or relugolix-containing products (e.g., Myfembree), greater than or equal to 6 months of treatment with Orilissa 200 mg twice daily

DURATION OF APPROVAL (DOA)

- 4752-A: Total additive duration: 24 months (see chart)

Cumulative months of prior treatment with an elagolix- and/or relugolix-containing product	Duration of Approval (in months)
No prior treatment	12
≤ 12	12
13	11
14	10
15	9
16	8
17	7
18	6
19	5
20	4
21	3
22	2
23	1

REFERENCES

1. Lupaneta Pack [package insert]. North Chicago, IL: AbbVie Inc.; June 2015.
2. Lupron Depot [package insert]. North Chicago, IL: AbbVie Inc.; October 2023.
3. Myfembree [package insert]. Brisbane, CA: Myovant Sciences, Inc.; August 2023.
4. Oriahnn [package insert]. North Chicago, IL: AbbVie Inc.; June 2023.
5. Orilissa [package insert]. North Chicago, IL: AbbVie Inc.; June 2023.
6. Synarel [package insert]. New York, NY: Pfizer Inc.; January 2023.
7. Zoladex 3.6 mg [package insert]. Deerfield, IL: TerSera Therapeutics LLC; March 2023.
8. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. https://online.lexi.com. Accessed December 05, 2023.
9. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 12/05/2023).
10. Schrager S, Falleroni J, Edgoose J. Evaluation and treatment of endometriosis. *Am Fam Physician*. 2013;87(2):107.
11. Management of endometriosis. Practice Bulletin No. 114. American College of Obstetricians and Gynecologists. *Obstet Gynecol*. 2010;116:223-236.
12. Edi R, Cheng T. Endometriosis: Evaluation and Treatment. *Am Fam Physician*. 2022;106(4):397-404.