UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 2216-5
Program	Prior Authorization/Medical Necessity
Medication	Oriahnn (elagolix and estradiol/norethindrone), MyFembree (relugolix and estradiol hemihydrate/norethindrone)
P&T Approval Date	9/2020, 8/2021, 1/2022, 9/2022, 2/2023
Effective Date	5/1/2023; Oxford only: 5/1/2023

1. Background:

Oriahnn, elagolix, co-packaged with estradiol/norethindrone, and MyFembree, relugolix co-packaged with estradiol hemihyrate/norethindrone, are gonadotropin-releasing hormone (GnRH) receptor antagonists co-packaged with a combined oral contraceptive, is indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women. Myfembree is also indicated for the management of moderate to severe pain associated with endometriosis in premenopausal women.

2. Coverage Criteria[a]:

A. Uterine Fibroids

1. **Initial Authorization**

a. **MyFembree and Oriahnn** will be approved based on **all** of the following criteria:

1) Diagnosis of uterine fibroids (leiomyomas)

-AND-

2) Used for the management of heavy menstrual bleeding

-AND-

3) History of trial and failure[b], contraindication, or intolerance after a three-month trial to **one** of the following:

a) Estrogen/progestin contraceptive (e.g. Loestrin FE)
b) Progestin-releasing intrauterine devices (IUDs) (e.g. Mirena)
c) Progestin-only contraceptive [e.g., norethindrone (generic Micronor)]

-AND-

4) Prescribed by or in consultation with **one** of the following:

a) Obstetrics/Gynecologist (OB/GYN)
b) Reproductive endocrinologist

Authorization will be issued for 6 months

2. **Reauthorization**

a. **MyFembree** and **Oriahnn** will be approved based on **all** of the following criteria**:**

1) Documentation of positive clinical response to therapy
2) Impact to bone mineral density has been considered
3) Treatment duration has not exceeded a total of 24 months

Authorization will be issued for 6 months up to a maximum of 24 months
NOTE: MyFembree and Oriahnn are indicated for a maximum of 24 months

B. Pain associated with Endometriosis

1. **Initial Authorization**

a. **MyFembree** will be approved based on **all** of the following criteria:

1) Diagnosis of moderate to severe pain associated with endometriosis

-AND-

2) History of trial and failure[b] (e.g., inadequate pain relief), contraindication or intolerance after a three-month trial of **two** analgesics (e.g., ibuprofen, meloxicam, naproxen)

-AND-

3) History of trial and failure[b], contraindication, or intolerance after a three-month trial to **one** of the following:

a) Hormonal contraceptives
b) Progestins [e.g., norethindrone (generic Aygestin)]

-AND-

4) Prescribed by or in consultation with **one** of the following:

a) Obstetrics/Gynecologist (OB/GYN)
b) Reproductive endocrinologist

Authorization will be issued for 6 months

2. **Reauthorization**

a. **Myfembree** will be approved based on **all** of the following criteria**:**

(1) Documentation of positive clinical response to therapy
(2) Impact to bone mineral density has been considered
(3) Treatment duration has not exceeded a total of 24 months

Authorization will be issued for 6 months up to a maximum of 24 months
NOTE: MyFembree is indicated for a maximum of 24 months

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.
[b] For Connecticut business, only a 60 day trial will be required. For Kentucky and Mississippi business, only a 30 day trial will be required.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Oriahnn [package insert]. North Chicago, IL: AbbVie Inc.; August 2021
2. MyFembree [package insert]. Brisbane, CA: Myovant Sciences, Inc.; September 2022.
3. Sabry, M, Al-Hendy, Ayman. Medical Treatment of Uterine Leiomyoma. *Reprod Sci*. 2012:19(4):339-53.
4. The American College of Obstetricians and Gynecologists. Management of endometriosis. Practice Bulletin 114. July 2010 (Reaffirmed 2018).

Program	Prior Authorization/Medical Necessity – Oriahnn, MyFembree
Change Control	
Date	Change
9/2020	New program
8/2021	Annual review. Added MyFembree.
1/2022	Removed the tranexamic acid requirement. Updated the state mandate language. Updated references.
9/2022	Added new indication for pain associated with endometriosis for Myfembree. Updated state mandate language to include Mississippi.
2/2023	Removed the criteria that patient is premenopausal. Updated references.