

Initial Prior Authorization

Oriahnn

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Oriahnn	elagolix/estradiol/norethindrone acetate

Indications

FDA-approved Indications

Oriahnn is indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women.

Limitations of Use

Use of Oriahnn should be limited to 24 months due to the risk of continued bone loss, which 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 of the following criteria are 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 must not have 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)

- 3960-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

Reference number(s)
3960-A

References

1. Oriahnn [package insert]. North Chicago, IL: AbbVie Inc.; June 2023.
2. Myfembree [package insert]. Marlborough, MA: Sumitomo Pharma America, Inc.; July 2024.
3. Orilissa [package insert]. North Chicago, IL: AbbVie Inc.; June 2023.
4. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed November 29, 2024.
5. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 11/29/2024).