AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Orilissa	Page:	1 of 2
Effective Date:	6/26/2024	Last Review Date:	6/5/2024

Applies to:	☐Illinois	☐Florida	☐Michigan
	☒New Jersey	☒Maryland	☒Florida Kids
	☒Pennsylvania Kids	☒Virginia	☐Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Orilissa under the patient's prescription drug benefit.

Description:

Orilissa is indicated for the management of moderate to severe pain associated with endometriosis.

Limitations of Use:
Limit the duration of use based on the dose and coexisting condition.

Applicable Drug List:

Orilissa

Policy/Guideline:

Criteria for Approval:

Note: Requests for Orilissa 200mg will not be approved for a cumulative duration of more than 6 months.

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for the management of moderate to severe pain associated with endometriosis

AND

- 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

AND

  - If the patient has not previously received treatment with an elagolix-containing product (e.g., Oriahnn, Orilissa) or a relugolix-containing product (e.g., Myfembree), the patient will receive 150 mg once daily of the requested drug OR 200 mg twice daily of the requested drug

AND

  - Patient has had a trial and inadequate treatment response, intolerance, or a contraindication to formulary combined estrogen-progestin contraceptives in combination with nonsteroidal anti-inflammatory drugs (NSAIDs) or a formulary progestin-only contraceptive in combination with NSAIDs if the patient is unable to take or prefers to avoid combination contraceptives

OR

- 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: A) 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), B) Greater than or equal to 6 months of treatment with Orilissa 200 mg twice daily

Duration of Approval Limits apply.

Approval Duration and Quantity Restrictions:

Approval: Total cumulative duration of 24 months

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 06, 2023.
9. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 12/06/2023).
10. Schrager S, Falleroni J, Edgoose J. Evaluation and treatment of endometriosis. *Am Fam Physician*. 2013;87(2):107-13.
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.