



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Orilissa

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Effective Date: 2/1/2024

Last Review Date: 10/24/2023

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|-------------|---|--|--|
| Applies to: | <input type="checkbox"/> Illinois | <input type="checkbox"/> Florida | <input checked="" type="checkbox"/> Florida Kids |
| | <input checked="" type="checkbox"/> New Jersey | <input checked="" type="checkbox"/> Maryland | <input type="checkbox"/> Michigan |
| | <input checked="" type="checkbox"/> Pennsylvania Kids | <input checked="" type="checkbox"/> Virginia | <input type="checkbox"/> 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



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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.; July 2022.
3. Myfembree [package insert]. Brisbane, CA: Myovant Sciences, Inc.; September 2022.
4. Oriahnn [package insert]. North Chicago, IL: AbbVie Inc.; August 2021.
5. Orilissa [package insert]. North Chicago, IL: AbbVie Inc.; February 2021.
6. Synarel [package insert]. New York, NY: Pfizer Inc.; April 2022.
7. Zoladex [package insert]. Deerfield, IL: TerSera Therapeutics LLC; December 2020.
8. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2022; Accessed November 22, 2022.
9. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com>. Accessed November 22, 2022.
10. Schragger 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.