

PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

ORILISSA
(elagolix)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

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

Limitation of Use:

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

COVERAGE CRITERIA

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 150mg once daily of the requested drug OR 200mg twice daily of the requested drug

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 200mg twice daily

Duration of Approval Limits apply. [The duration of approval will be entered based upon the patient's previous use with elagolix-containing and/or relugolix-containing products; the total cumulative amount of time that the patient will be approved for elagolix-containing and/or relugolix-containing products will not exceed 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.; March 2020.
3. Myfembree [package insert]. Brisbane, CA: Myovant Sciences, Inc.; May 2021.
4. Oriahnn [package insert]. North Chicago, IL: AbbVie Inc.; May 2020.
5. Orilissa [package insert]. North Chicago, IL: AbbVie Inc.; February 2021.
6. Synarel [package insert]. New York, NY: Pfizer Inc.; December 2020.
7. Zoladex [package insert]. Deerfield, IL: TerSera Therapeutics LLC; February 2020.
8. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. <http://online.lexi.com/>. Accessed December 2020.

9. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. <http://www.micromedexsolutions.com/>. Accessed December 2020.
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;116:223-36.