

<b>Policy Name:</b>	<b>Orilissa (elagolix)</b>	<b>Policy #:</b>	<b>2679P</b>
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## Purpose of the Policy

The purpose of this policy is to define coverage criteria for Orilissa (elagolix) for the treatment of moderate to severe pain associated with endometriosis.

## Statement of the Policy

Health Alliance Medical Plans will approve the use of Orilissa (elagolix) if the following criteria are met.

## Criteria

### 1. Coverage Criteria

- 1.1 Diagnosis of moderate to severe pain associated with endometriosis
- 1.2 Age 18 years or older
- 1.3 Prescribed by or in consultation with an obstetrician-gynecologist (women's health doctor)
- 1.4 Documented failure, intolerance, or contraindication to a 3-month trial of non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen AND oral contraceptives

### 2. Exclusion Criteria

- 2.1 Orilissa will not be covered if the member is concurrently receiving therapy with a GnRH agonist or antagonist.
- 2.2 Continued coverage is not allowed after the originally approved regimen is completed (150mg daily for 24 months OR 200mg twice daily for 6 months)
  - Orilissa is associated with dose-dependent irreversible decrease in bone mineral density

### 3. Quantity Limit

- 3.1 150mg: #30/30 days
- 3.2 200mg: #60/30 days

### 4. Approval Period

- 4.1 Endometriosis – 24 months (150mg daily dose)
- 4.2 Endometriosis with dyspareunia – 6 months (200mg twice daily dose)

## CPT Codes

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## HCPCS Codes

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## References

1. Orilissa (elagolix) [prescribing information]. North Chicago, IL: AbbVie Inc; June 2023.
2. Taylor HS, Giudice LC, Lessey BA, et al. Treatment of Endometriosis-Associated Pain with Elagolix, an Oral GnRH Antagonist. *N Engl J Med* 2017;377: 28-40.
3. Saridogan E, Tomassetti C, van Hanegem N, et al. ESHRE guideline: management of women with endometriosis. *Hum Reprod Open*. 2022 Feb 26;2022(2):hoac009.
4. Management of Endometriosis. ACOG Practice Bulletin. Clinical Management Guidelines for Obstetrician Gynecologists. Number 114. 2010 (reaffirmed 2018). *Obstet & Gynecol*. 2010;116(1):223-236.

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### DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.