

**Orilissa (elagolix)  
Effective 04/01/19**

<b>Plan</b>	<input checked="" type="checkbox"/> MassHealth <input checked="" type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Specialty Limitations</b>	N/A		
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	<b>Non-Specialty Medications</b>		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	<b>Medical Specialty Medications (NLX)</b>		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
<b>Exceptions</b>	N/A		

**Overview**

Orilissa (elagolix) is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the management of moderate to severe pain associated with endometriosis.

**Coverage Guidelines**

Members will be granted approval of Orilissa when ALL the following criteria have been met and documentation has been submitted:

1. Member has OB/BYN documented diagnosis of endometriosis with moderate to severe pain
2. Member is 18 years of age or older
3. Member has had an insufficient response or intolerance to generic alternatives in at least two of the following therapeutic drug classes:
  - o Nonsteroidal anti-inflammatory drugs (NSAIDs)
  - o Hormonal contraceptives
  - o Oral or depot medroxyprogesterone
4. Member has had an inadequate response, adverse reaction, or contraindication to Lupron

**Continuation of Therapy**

Reauthorization requires physician documentation of improvement of member’s condition.

**Limitations**

- Initial approvals will be granted for the following:
  - o Endometriosis without dyspareunia (150mg tablets) – 6 months
  - o Endometriosis with dyspareunia (200mg tablets) – 6 months (maximum)
- Reauthorization will be granted for the following:
  - o Endometriosis without dyspareunia (150mg tablets) – 6 months



- Endometriosis with dyspareunia (200mg tablets) – Maximum of 6 months
- Reauthorizations of Orilissa 200mg for the treatment of moderate to severe pain associated with endometriosis with dyspareunia will not be granted.

### References

1. Orilissa (elagolix) [prescribing information]. North Chicago, IL: AbbVie Inc; July 2018.
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.
3. Surrey E, Taylor HS, Giudice L, et al. Long-Term Outcomes of Elagolix in Women With Endometriosis: Results From Two Extension Studies. *Obstet Gynecol* 2018; 132:147.
4. Struthers RS, Nicholls AJ, Grundy J, et al. Suppression of gonadotropins and estradiol in premenopausal women by oral administration of the nonpeptide gonadotropin-releasing hormone antagonist elagolix. *J Clin Endocrinol Metab*. 2009;94(2):545-551. doi:10.1210/jc.2008-1695. [PubMed 19033369]

### Review History

02/20/19 – Reviewed

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