

All requests for **Orilissa (elagolix)** require a Prior Authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Orilissa (elagolix) Prior Authorization Criteria:

Coverage may be provided with a diagnosis of moderate to severe pain associated with endometriosis and the following criteria is met:

- The member is premenopausal and 18 years of age or older
- Diagnosis of endometriosis confirmed by either:
 - Laparoscopy
 - Chart documentation of an adequate work-up that includes the clinical rationale for the diagnosis
- History of trial and failure (e.g., inadequate pain relief), contraindication or intolerance to two NSAIDS
- History of trial and failure , contraindication, or intolerance after a three month trial to one of the following:
 - Hormonal contraceptives
 - Progestins (e.g., norethindrone)
- Prescribed by or in consultation with a obstetrics/gynecologist (OB/GYN) or reproductive endocrinologist
- The member must have normal liver function or mild to moderate hepatic impairment
- The member must not have a contraindication to the requested medication including:
 - Pregnancy
 - Known osteoporosis
 - Severe hepatic impairment
 - Organic anion transporting polypeptide (OATP) 1B1 inhibitors that significantly increase elagolix plasma concentrations
 - Hypersensitivity reactions
- For non-preferred agents, the member has had a trial and failure of a preferred agent or submitted a clinical reason for not having a trial of a preferred agent
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
 - Documentation of a positive clinical response to therapy (e.g. pain relief)
- **Reauthorization Duration of Approval:** 6 months
 - Orilissa 150mg: maximum of 24 months; Maximum of 6 months if member has moderate hepatic impairment (Child-Pugh Class B)
 - Orilissa 200 mg: maximum of 6 months; no reauthorization permitted



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Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

Drugs are authorized in generic form unless the branded product is on the preferred drug list or the prescriber has indicated in writing that the branded product is medically necessary. If only the branded product is on the preferred drug list, the generic form will be considered non-preferred and shall not require the prescriber to indicate in writing that the branded product is medically necessary.

ORLISSA (ELAGOLIX) PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX:** (855) 476-4158
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE:** (844) 325-6251 Mon-Fri 8:00am to 7:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? <input type="checkbox"/> Yes <input type="checkbox"/> No		Date Medication Initiated:
Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? <input type="checkbox"/> Yes <input type="checkbox"/> No		

Billing Information

This medication will be billed: at a pharmacy **OR** medically, JCODE: _____
Place of Service: Hospital Provider's office Member's home Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis:
 Moderate to severe pain associated with endometriosis, Other: _____ ICD-10: _____
 Has the diagnosis been confirmed by laparoscopy? Yes No (must provide chart documentation of an evaluation to exclude other diagnoses)
 Has the member tried and failed both: NSAIDs (list below) Contraceptives or progestins (list below)
 Is the member premenopausal? Yes No
 Does the member have any contraindications to therapy? Yes No

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

Has the member experienced a positive clinical response to therapy? Yes No
Please describe:

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date



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