**Request for Prior Authorization for Orilissa (elagolix)** Website Form - www.highmarkhealthoptions.com Submit request via: Fax - 1-855-476-4158

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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
- Diagnosis of endometriosis confirmed by either:
  - Laparoscopy
  - o 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
- Must be age-appropriate according to FDA-approved labeling, nationally recognized compendia, or evidence-based practice guidelines
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- 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
  - o Known osteoporosis
  - Severe hepatic impairment
  - o 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
- **Initial Duration of Approval:** 6 months
- Reauthorization criteria
  - o Documentation of a positive clinical response to therapy (e.g. pain relief)
- **Reauthorization Duration of Approval:** 6 months
  - o Orilissa 150mg: maximum of 24 months; Maximum of 6 months if member has moderate hepatic impairment (Child-Pugh Class B)

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o Orilissa 200 mg: maximum of 6 months; no reauthorization permitted

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 peerreviewed 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.



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## ORILISSA (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: Height: Member weight: REQUESTED DRUG INFORMATION Medication: Strength: Refills: Directions: **Ouantity:** Is the member currently receiving requested medication? Yes 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? Yes No **Billing Information** This medication will be billed:  $\square$  at a pharmacy **OR**  $\square$  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: \_\_\_\_\_ 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? \(\subseteq\) Yes \(\subseteq\) No Does the member have any contraindications to therapy? \( \subseteq \text{Yes} \subseteq \text{No} \) **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? \( \subseteq \text{Yes} \subseteq \text{No} \) Please describe: SUPPORTING INFORMATION or CLINICAL RATIONALE **Prescribing Provider Signature** Date



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