HIGHMARK HEALTH OPTIONS

Updated: 09/2022
DMMA Approved: 10/2022

Request for Prior Authorization for Oriahnn (elagolix/estradiol/norethindrone acetate) and Myfembree (relugolix, estradiol and norethindrone acetate)
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

All requests for **Oriahnn** (elagolix/estradiol/norethindrone acetate) and **Myfembree** (relugolix, estradiol and norethindrone acetate) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Oriahnn (elagolix/estradiol/norethindrone acetate) and Myfembree (relugolix, estradiol and norethindrone acetate) Prior Authorization Criteria:

Coverage may be provided with a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) and the following criteria is met:

- The member is premenopausal and 18 years of age or older
- The member has heavy menstrual bleeding defined as having at least two menstrual cycles with greater than 80 mL of menstrual blood loss (MBL) as assessed by alkaline hematin (AH) method
- History of trial and failure, contraindication, or intolerance to one of the following:
    - Hysteroscopic myomectomy (if the fibroids are in an appropriate anatomic location)
    - Estrogen-progestin contraceptives (three month trial)
    - Progestins (e.g., norethindrone; IUD or oral therapy) (three month trial)
    - Tranexamic acid (three month trial) *may require prior authorization
- Prescribed by or in consultation with a obstetrics/gynecologist (OB/GYN) or reproductive endocrinologist
- Member does not have any known contraindications to therapy.
- 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:** 12 months
- **Reauthorization criteria**
    - Documentation of a positive clinical response to therapy demonstrated by a reduction in MBL volume or an improvement in hemoglobin (if applicable).
- **Reauthorization Duration of Approval:** 12 months
    - No reauthorization permitted after 24 months of therapy due to risk of potentially irreversible bone loss.

Myfembree ONLY:

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 not have a contraindication to the requested medication.
- 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:** 12 months
- **Reauthorization criteria**
    - Documentation of a positive clinical response to therapy (e.g. pain relief)
- **Reauthorization Duration of Approval:** 12 months
    - No reauthorization permitted after 24 months of therapy due to risk of potentially irreversible bone loss.

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.

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ORIAHNN (ELAGOLIX, ESTRADIOL, NORETHINDRONE ACETATE) AND MYFEMBREE (RELUGOLIX, ESTRADIOL, AND NORETHINDRONE ACETATE)
PRIOR AUTHORIZATION FORM- Page 1 of 2

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 Monday through Friday 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? ☐ 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: ☐ 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:
☐ Heavy menstrual bleeding (MBL) associated with uterine fibroids, ☐ Moderate to severe pain associated with endometriosis
ICD-10: _____
Is the member premenopausal? ☐ Yes ☐ No
Has the member had heavy menstrual bleeding during at least two menstrual cycles with greater than 80 mL of menstrual blood loss (MBL) as assessed by alkaline hematin (AH) method? ☐ Yes ☐ No
Has the member tried and failed, have a contraindication or intolerance to one of the following: ☐ Hysteroscopic myomectomy ☐ Estrogen-progestin contraceptives *(list below)* ☐ Progestin contraceptives (IUD or oral therapy) *(list below)*
Does the member have any contraindications to therapy? ☐ Yes ☐ No
Endometriosis diagnosis:
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)

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PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 2 OF 2

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

MEMBER INFORMATION

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

REAUTHORIZATION

Has the member experienced a positive clinical response to therapy demonstrated by a reduction in MBL volume or an improvement in hemoglobin (if applicable)? ☐ Yes ☐ No
Has the member experienced a positive clinical response to therapy such as pain relief or a decrease in pain medication?
☐ Yes ☐ No

Please describe:

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date