Highmark Wholecare
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

I. Requirements for Prior Authorization of Pituitary Suppressive Agents, LHRH

A. Prescriptions That Require Prior Authorization

All prescriptions for Pituitary Suppressive Agents, LHRH must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Pituitary Suppressive Agent, LHRH, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Pituitary Suppressive Agent, LHRH for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling or a medically accepted indication; **AND**

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Is prescribed a dose and duration of therapy that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

4. Does not have a contraindication to the prescribed medication; **AND**

5. For a diagnosis of central precocious puberty, **all** of the following:

   a. Is prescribed the Pituitary Suppressive Agent, LHRH by or in consultation with a pediatric endocrinologist,
   b. Is ≤ 11 years of age for females or ≤ 12 years of age for males,
   c. Experienced onset of secondary sexual characteristics earlier than 8 years in females and 9 years in males;

   AND

6. For an adolescent with gender dysphoria, **both** of the following:

   a. Is prescribed the Pituitary Suppressive Agent, LHRH by or in consultation with a pediatric endocrinologist, adolescent medicine specialist, or medical provider with experience and/or training in transgender medicine
   b. Is prescribed the Pituitary Suppressive Agent, LHRH in a manner consistent with the current World Professional Association for Transgender Health Standards of Care for the Health of Transgender and Gender Diverse People;

   AND

7. For an adult with gender dysphoria, **both** of the following:

   a. Is prescribed the Pituitary Suppressive Agent, LHRH by or in consultation with an endocrinologist or medical provider with experience and/or training in transgender medicine
   b. Is prescribed the Pituitary Suppressive Agent, LHRH in a manner consistent with the current World Professional Association for Transgender Health Standards of Care for the Health of Transgender and Gender Diverse People;

   AND

8. For a diagnosis of endometriosis, **all** of the following:

   a. Has **one** of the following:
      i. A diagnosis of endometriosis confirmed by laparoscopy
      ii. A diagnosis of endometriosis supported by chart documentation of an adequate work-up that includes the clinical rationale for the diagnosis,

   b. Has a history of **both** of the following:
      i. Therapeutic failure of or a contraindication or an intolerance to non-steroidal anti-inflammatory drugs
      ii. Therapeutic failure (based on a 3-month trial) of or a contraindication or an intolerance to oral contraceptives,

   c. Is prescribed the Pituitary Suppressive Agent, LHRH by or in consultation with a gynecologist;

   AND

9. For preservation of ovarian function, is receiving cancer treatment that is associated with premature ovarian failure (based on NCCN guidelines or peer-reviewed medical literature); **AND**

10. For Oriahnn (elagolix, estradiol, norethindrone; elagolix) and Myfembree (relugolix/estradiol/norethindrone acetate) for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women, has a history of therapeutic failure (based on a 3-month trial) of or a contraindication or an intolerance to contraceptives; **AND**

11. For an elagolix-containing agent or Myfembree (relugolix/estradiol/norethindrone acetate), if the beneficiary has a history of depression and/or suicidal thoughts or behaviors or is currently receiving treatment for depression and/or suicidal thoughts or behavior, has a behavioral health assessment prior to use; **AND**

12. For a non-preferred Pituitary Suppressive Agent, LHRH, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Pituitary Suppressive Agents, LHRH approved or medically accepted for the beneficiary's indication. See the Preferred Drug List for the list of preferred Pituitary Suppressive Agents, LHRH at: https://papdl.com/preferred-drug-list;

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Pituitary Suppressive Agent, LHRH. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

Highmark Wholecare
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

PITUITARY SUPPRESSIVE AGENTS, LHRH PRIOR AUTHORIZATION FORM *(form effective 1/3/2022)*

☐New request ☐Renewal request	Total # of pgs: _____	Prescriber name:	
Name of office contact:		Specialty:	
Contact's phone number:		NPI:	State license #:
LTC facility contact/phone:		Street address:	
Beneficiary name:		Suite #:	City/State/Zip:
Beneficiary ID#:	DOB:	Phone:	Fax:

CLINICAL INFORMATION

Drug requested:	Strength:	
Directions/frequency:	Quantity:	Refills:
Diagnosis *(submit documentation)*:	Dx code (*required*):	
For a non-preferred Pituitary Suppressive Agent, LHRH: Does the beneficiary have a history of trial and failure of or contraindication or intolerance to the preferred drugs in this class approved or medically accepted for treatment of the beneficiary's condition? *Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred drugs in this class.*	☐Yes – *Submit documentation.* ☐No	

Complete the section(s) below applicable to the beneficiary and this request and SUBMIT DOCUMENTATION for each item.

☐**For the treatment of CENTRAL PRECOCIOUS PUBERTY:**
- ☐Is prescribed the medication by or in consultation with a pediatric endocrinologist
- ☐Is female:
  - ☐Is ≤11 years of age
  - ☐Experienced onset of secondary sexual characteristics earlier than 8 years of age
- ☐Is male:
  - ☐Is ≤12 years of age
  - ☐Experienced onset of secondary sexual characteristics earlier than 9 years of age

☐**For the treatment of GENDER DYSPHORIA:**
- ☐Is prescribed the medication by or in consultation with an adult or pediatric endocrinologist or other provider with experience/training in transgender medicine
- ☐Is prescribed the medication in a manner consistent with current WPATH standards of care or other medical literature

☐**For the treatment of ENDOMETRIOSIS:**
- ☐Is prescribed the medication by or in consultation with a gynecologist
- ☐Diagnosis confirmed by laparoscopy
- ☐Diagnosis supported by chart documentation of adequate work-up that includes the clinical rationale for the diagnosis
- ☐Tried and failed NSAIDs or has a contraindication or intolerance to NSAIDs
- ☐Failed a 3-month trial of oral contraceptives or has a contraindication or intolerance to oral contraceptives

☐**For PRESERVATION OF OVARIAN FUNCTION:**
- ☐Is receiving cancer treatment that is associated with premature ovarian failure based on NCCN guidelines or peer-reviewed medical literature

☐**For MYFEMBREE (relugolix/estradiol/norethindrone), ORIAHNN (elagolix/estradiol/norethindrone + elagolix), and ORILISSA (elagolix):**
- ☐Has a history of depression and/or suicidal thoughts or behaviors OR is receiving treatment for depression and/or suicidal thoughts or behaviors
  - ☐Had a behavioral health assessment prior to use of the requested medication

☐**For MYFEMBREE (relugolix/estradiol/norethindrone) and ORIAHNN (elagolix/estradiol/norethindrone + elagolix):**
- ☐Is being treated for **HEAVY MENSTRUAL BLEEDING ASSOCIATED WITH UTERINE LEIOMYOMAS (FIBROIDS)**
- ☐Is pre-menopausal
- ☐Tried and failed a 3-month trial of or has a contraindication or intolerance to contraceptives

PLEASE FAX COMPLETED FORM TO HIGHMARK WHOLECARE – PHARMACY DIVISION

Prescriber Signature:	**Date**: