# Clinical Policy: Pituitary Suppressive Agents, LHRH

Reference Number: PHW.PDL.224
Effective Date: 01/01/2020
Last Review Date: 11/2023

Revision Log

**Policy/Criteria**
*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of PA Health and Wellness® that Luteinizing Hormone-Releasing Hormone Pituitary Suppressive Agents are **medically necessary** when the following criteria are met:

## 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 member:

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 member 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 member's indication; **AND**

13. If a prescription for a Pituitary Suppressive Agent, LHRH is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override.

    NOTE: If the member 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 member, 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 member.

D. **Approval Duration: 6 months**

E. References

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2. Schmidt L, Levine R. Psychological Outcomes and Reproductive Issues Among Gender Dysphoric Individuals. Endocrinol Metab Clin N Am. 44(2015)773-785.
3. Medical Assistance Bulletin Number 99-16-11, Subject: Federal Final Rule, Nondiscrimination in Health Programs and Activities" and Implications for Coverage of Services Related to Gender Transition; http://www.dhs.pa.gov/publications/bulletinsearch/bulletinselected/index.htm?bn= 99-16-11&o=N&po=OMAP&id=07/18/2016.
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7. Oriahnn [package insert]. North Chicago, IL. AbbVie, Inc. May 2020.
8. National Comprehensive Cancer Network. Adolescent and Young Adult (AYA) Oncology (Version 1.2020). https://www.nccn.org/professionals/physician_gls/pdf/aya.pdf. Accessed July 9, 2020.
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10. Harrington J, Palmert MR. Definition, etiology, and evaluation of precocious puberty. UpToDate. Accessed August 10, 2021.
11. Harrington J, Palmert MR. Treatment of precocious puberty. UpToDate. Accessed August 10, 2021.
12. Myfembree [package insert]. Mississauga, Ontario. Myovant. May 2021.
13. Coleman E, Radix AE, Bouman WP, et al. Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. Int J Transgend Health. 2022 Sep 6;23(Suppl 1):S1-S259. doi: 10.1080/26895269.2022.2100644. PMID: 36238954; PMCID: PMC9553112.

| Reviews, Revisions, and Approvals | Date |
|---|---|
| Policy created | 01/01/2020 |
| Q3 2020 annual review: no changes. | 07/2020 |
| Q1 2021: policy revised according to DHS revisions effective 01/05/2021 | 11/2020 |
| Q1 2022: policy revised according to DHS revisions effective 01/03/2022 | 10/2021 |
| Q1 2023: policy revised according to DHS revisions effective 01/09/2023 | 10/2022 |
| Q1 2024: policy revised according to DHS revisions effective 01/08/2024 | 11/2023 |