


| | | |
|---|--|---------------------------------|
| ISSUE DATE December 8, 2022 | EFFECTIVE DATE January 9, 2023 | NUMBER *See below |
| SUBJECT Prior Authorization of Pituitary Suppressive Agents, LHRH – Pharmacy Services | BY  Sally A. Kozak, Deputy Secretary Office of Medical Assistance Programs | |

IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISE to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: <https://www.dhs.pa.gov/providers/Providers/Pages/PROMISE-Enrollment.aspx>.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Pituitary Suppressive Agents, LHRH submitted for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program. The guidelines to determine the medical necessity of Pituitary Suppressive Agents, LHRH will be utilized in the fee-for-service and managed care delivery systems. Providers rendering services to MA beneficiaries in the managed care delivery system should address any questions related to the prior authorization of Pituitary Suppressive Agents, LHRH to the appropriate managed care organization.

BACKGROUND:

| | | | |
|-----------|----------|----------|----------|
| *01-22-72 | 09-22-71 | 27-22-59 | 33-22-69 |
| 02-22-56 | 11-22-56 | 30-22-62 | |
| 03-22-55 | 14-22-56 | 31-22-75 | |
| 08-22-80 | 24-22-63 | 32-22-56 | |

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll-free number for your provider type.

Visit the Office of Medical Assistance Programs website at <https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx>.

The Department of Human Services' (Department) Pharmacy and Therapeutics (P&T) Committee reviews published peer-reviewed medical literature and recommends the following:

- Preferred or non-preferred status for new drugs and products in therapeutic classes already included in the Preferred Drug List (PDL).
- Changes in the status of drugs and products on the PDL from preferred to non-preferred and non-preferred to preferred.
- New quantity limits.
- Therapeutic classes of drugs and products to be added to or deleted from the PDL.
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

DISCUSSION:

During the September 14, 2022, meeting, the P&T Committee recommended revision to the guidelines to determine medical necessity of Pituitary Suppressive Agents, LHRH to clarify the guideline related to a behavioral health assessment for beneficiaries with a history of depression and/or suicidal thoughts or behavior.

The revisions to the guidelines to determine medical necessity of prescriptions for Pituitary Suppressive Agents, LHRH submitted for prior authorization, as recommended by the P&T Committee, were subject to public review and comment and subsequently approved for implementation by the Department.

PROCEDURE:

The procedures for prescribers to request prior authorization of Pituitary Suppressive Agents, LHRH are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to Pituitary Suppressive Agents, LHRH) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs and products that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

RESOURCES:

Prior Authorization of Pharmaceutical Services Handbook – SECTION I
Pharmacy Prior Authorization General Requirements

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Pharmacy-Prior-Authorization-General-Requirements.aspx>

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Clinical-Guidelines.aspx>

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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 is 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 transsexual, transgender, and gender nonconforming people;

AND

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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 current medical literature;

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 **all** 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**

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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>; **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 the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

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.

D. References

1. Hembree WC, Cohen-Kettenis P, Delemarre-van de Waal HA, et al. Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2009;94(9):3132-3154.
2. Schmidt L, Levine R. Psychological Outcomes and Reproductive Issues Among Gender Dysphoric Individuals. Endocrinol Metab Clin N Am. 44(2015)773-785.
3. Coleman E, Bockting W, Botzer M, et al. Standards of care for the health of transsexual, transgender, and gender-nonconforming people, version 7. Int J Transgenderism 2011;13:165-232.
4. 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>.
5. Schenken RS, Barbieri RL, Eckler K. Endometriosis: Pathogenesis, clinical features, and diagnosis. UpToDate. Accessed August 22, 2019.

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

6. Schenken RS, Barbieri RL, Eckler K. Endometriosis: Treatment of pelvic pain. UpToDate. Accessed August 22, 2019.
7. Orilissa [package insert]. North Chicago, IL. AbbVie, Inc. July 2018.
8. Oriahnn [package insert]. North Chicago, IL. AbbVie, Inc. May 2020.
9. 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.
10. Kaplowitz P, Block C. Evaluation and referral of children with signs of early puberty. Pediatrics. 2016; 137(1); e20153732. Available at <https://pediatrics.aappublications.org/content/pediatrics/early/2015/12/11/peds.2015-3732.full.pdf>
11. Harrington J, Palmert MR. Definition, etiology, and evaluation of precocious puberty. UpToDate. Accessed August 10, 2021.
12. Harrington J, Palmert MR. Treatment of precocious puberty. UpToDate. Accessed August 10, 2021.
13. Myfembree [package insert]. Mississauga, Ontario. Myovant. May 2021.