pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
January 31, 2017	January 31, 2017	*See below

SUBJECT

Prior Authorization of Pituitary Suppressive Agents, LHRH - Pharmacy Services

BY

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Office of Medical Assistance Programs

IMPORTANT REMINDER: All providers must revalidate their MA enrollment every 5 years. Providers should log into PROMISe to check their revalidation date and submit a revalidation application at least 60 days prior. Enrollment (revalidation) applications may be found at http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994.

PURPOSE:

The purpose of this bulletin is to:

1. Inform providers that the Department of Human Services (Department) will require prior authorization of Pituitary Suppressive Agents, LHRH.

2. Issue handbook pages that include instructions on how to request prior authorization of Pituitary Suppressive Agents, LHRH, including the type of medical information needed to evaluate requests for medical necessity.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program and providing services in the fee-for-service (FFS) delivery system, including pharmacy services to residents of long term care facilities.

BACKGROUND:

The Department's Drug Utilization Review (DUR) Board meets semi-annually to review provider prescribing and dispensing practices for efficacy, safety, and quality and to recommend interventions for prescribers and pharmacists through the Department's

*01-17-13	09-17-12	27-17-11	
02-17-11	11-17-11	30-17-12	
03-17-11	14-17-11	31-17-13	
08-17-12	24-17-11	32-17-11	33-17-12

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 Web site at
http://www.dhs.state.pa.us/provider/healthcaremedicalassistance/index.htm

Prospective Drug Use Review (ProDUR) and Retrospective Drug Use Review (RetroDUR) programs.

DISCUSSION:

During the September 26, 2016 meeting, the DUR Board recommended that the Department require prior authorization of all prescriptions for Pituitary Suppressive Agents, LHRH and make additions to the existing medical necessity guidelines. Previously, prior authorization was required only for non-preferred agents within this Preferred Drug List (PDL) class. However, in order to promote appropriate utilization of these drugs, the DUR Board recommended a prior authorization requirement for all agents in this class based on national treatment guidelines and medical literature. The additions to the medical necessity guidelines include guidelines for use of these agents by adolescents with gender dysphoria. The requirement for prior authorization and the guidelines to determine medical necessity, as recommended by the DUR Board, were subject to public review and comment, and subsequently approved for implementation by the Department. The requirements for prior authorization and clinical review guidelines to determine the medical necessity of Pituitary Suppressive Agents, LHRH are included in the attached updated provider handbook pages.

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 chapters 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 that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

SECTION II
Pituitary Suppressive Agents, LHRH

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

A. Prescriptions That Require Prior Authorization

Prescriptions for Pituitary Suppressive Agents, LHRH that meet the following conditions must be prior authorized.

1. A prescription for a preferred or a non-preferred Pituitary Suppressive Agent, LHRH. See Preferred Drug List (PDL) for the list of preferred Pituitary Suppressive Agents, LHRH at: https://papdl.com/preferred-drug-list

2. A prescription for a preferred or non-preferred Pituitary Suppressive Agents, LHRH with a prescribed quantity that exceeds the quantity limit.
   See Quantity Limits for the list of drugs with quantity limits at: http://www.dhs.state.pa.us/provider/doingbusinesswithdhs/pharmacyservices/quantitylimitslist/index.htm

B. Review of Documentation for Medical Necessity

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

1. The Pituitary Suppressive Agent, LHRH prescribed is for treatment of a condition that is a U.S. Food and Drug Administration (FDA) approved, or a medically accepted indication

AND

2. If the request is for a non-preferred Pituitary Suppressive Agent, LHRH, the recipient has a documented history of therapeutic failure, a contraindication to or intolerance of the preferred Pituitary Suppressive Agents, LHRH approved for the same indication

AND

3. If the Pituitary Suppressive Agent, LHRH is prescribed for adolescents with gender dysphoria, whether:

   a. The Pituitary Suppressive Agent, LHRH is prescribed by or in consultation with a pediatric endocrinologist,

adolescent medicine specialist or medical provider with experience and/or training in transgender medicine

AND

b. The drug is being prescribed in a manner consistent with the current World Professional Association for Transgender Health (WPATH) standards of care for the health of transsexual, transgender, and gender nonconforming people.

OR

4. Does not meet the clinical review guidelines listed above, but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

5. In addition, if a prescription for a Pituitary Suppressive Agent, LHRH is in 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.

C. Automated Prior Authorization

Prior authorization of a prescription for a Pituitary Suppressive Agent, LHRH at or below the quantity limit will be automatically approved when the PROMISe Point-of-Sale On-Line Claims Adjudication System verifies a record of paid claim(s) within 365 days prior to the date of service that documents that the guidelines to determine medical necessity listed above have been met.

D. 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 the request for 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 recipient.

References

1. Hembree WC, Cohen-Kettenis P, Delemarre-van de Waal HA, et al. Endrocrine 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