pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
November 13, 2020	January 5, 2021	*See below

SUBJECT

Prior Authorization of Progestational Agents – 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 Progestational Agents 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 Progestational Agents will be utilized in the fee-for-service delivery system and by the MA managed care organizations (MCOs) in Physical Health HealthChoices and Community HealthChoices. Providers rendering services in the MA managed care delivery system should address any questions related to the prior authorization of Progestational Agents to the appropriate managed care organization.

*01-20-40	09-20-39	27-20-35	33-20-36
02-20-33	11-20-33	30-20-32	
03-20-33	14-20-34	31-20-40	
08-20-43	24-20-33	32-20-32	

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

BACKGROUND:

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

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

DISCUSSION:

During the August 12, 2020, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of Progestational Agents:

- Addition of a guideline specific to non-preferred intravaginal Progestational Agents to account for the unique indications of these agents;
- Revision to the guideline specific to hydroxyprogesterone caproate that addresses the appropriate point in the gestation period to initiate treatment to reflect the U.S. Food and Drug Administration (FDA)-approved package labeling and specialist input;
- Addition of a guideline that agents in the Progestational Agents PDL class are subject to the guidelines in the Quantity Limits Chapter; and
- Revision to the Dose and Duration of Therapy for hydroxyprogesterone caproate to be consistent with FDA-approved package labeling.

The revisions to the guidelines to determine medical necessity of Progestational Agents, 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 Progestational Agents 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 Progestational Agents) 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

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

I. Requirements for Prior Authorization of Progestational Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Progestational Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Progestational Agent. See the Preferred Drug List (PDL) for the list of preferred Progestational Agents at: https://papdl.com/preferred-drug-list.

2. A Progestational Agent with a prescribed quantity that exceeds the quantity limit. 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.

3. A prescription for hydroxyprogesterone caproate.

B. Review of Documentation for Medical Necessity

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

1. For a non-preferred Progestational Agent, **one** of the following:

   a. Has a history of therapeutic failure, contraindication, or intolerance of the preferred Progestational Agents approved or medically accepted for the beneficary's indication
   b. For an intravaginal Progestational Agent, is prescribed the intravaginal Progestational Agent for treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration-approved package labeling OR a medically accepted indication, excluding use to promote fertility;

   AND

2. For hydroxyprogesterone caproate, **all** of the following:

   a. Is a pregnant female with a single fetus,

   b. Is between 16 weeks 0 days and 36 weeks 6 days gestation,

   c. Has a documented history of a prior spontaneous preterm singleton birth (defined as prior to 37 weeks gestation),

   d. Is being, or was, initiated into treatment between 16 weeks 0 days and 20 weeks 6 days,

e. Does not have a history of a contraindication to hydroxyprogesterone caproate;

AND

3. If a prescription for a Progestational Agent 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.

   NOTE: If the beneficiary 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 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 Progestational Agent. 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. Dose and Duration of Therapy

Approvals of requests for prior authorization of prescriptions for hydroxyprogesterone caproate will be consistent with the FDA-approved package labeling.

E. References

1. FDA Statement on Makena, November 8, 2011. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm27909 8.htm January 22, 2014 (Replacing May 14, 2012)
2. ACOG Committee Opinion Number 419, October 2008, Reaffirmed 2011. http://www.acog.org/~/media/Committee%20Opinions/Committee%20on%20 Obs tetric%20Practice/co419.ashx?dmc=1&ts=20120118T0911074525
3. Information Update on 17a-Hydroxyprogesterone Caproate (17P) from The American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine. http://www.acog.org/~/media/Announcements/20111013MakenaLtr.ashx?dmc =1&ts=20120118T0911074515
4. Makena® (package insert), AMAG Pharmaceuticals 2018. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a1998c1d-8337-4f00-8dcb-af3b54d39b77