Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: N/A**
Policy Number: PHW.PDL.151	**Effective Date: 01/01/2020** **Revision Date: 10/2021**
Policy Name: Progestational Agents	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☐ **Revised Policy***
- ✓ **Annual Review - No Revisions**
- ✓ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

Q1 2022 annual review: no changes.

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:**

Clinical Policy: Progestational Agents

Reference Number: PHW.PDL.151
Effective Date: 01/01/2020
Last Review Date: 10/2021

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 health plans affiliated with PA Health and Wellness® that Progestational Agents are **medically necessary** when the following criteria are met:

I. Requirements for Prior Authorization of Progestational Agents

A. Prescriptions That Require Prior Authorization

A prescription for a Progestational Agent that meets any of the following conditions must be prior authorized:

1. A prescription for a non-preferred Progestational Agent.

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

3. A prescription for hydroxyprogesterone caproate.

B. Review of Documentation for Prior Authorization

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 recipient:

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 PA.CP.PMN.59 Quantity Limit Override

   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. 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

- **hydroxyprogesterone caproate - up to a total of 21 doses to reach week 37 (through 36 weeks, 6 days) of gestation or delivery, whichever occurs first**
- **All other agents – duration of request or 12 months (whichever is less)**

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 Obstetric%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

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 annual review: no changes.	10/2021