# Clinical Policy: Progestational Agents

Reference Number: PHW.PDL.151
Effective Date: 01/01/2020
Last Review Date: 11/2024

**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 & 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.

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 member:

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 member'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. 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 member 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 member, 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 member.

D. Dose and Duration of Therapy

- **All agents – duration of request or 12 months (whichever is less)**

E. References

1. U.S. Food & Drug Administration. Makena (hydroxyprogesterone caproate injection) Information. *Postmarket Drug Safety Information for Patients and Providers.* April 6, 2023. https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/makena-hydroxyprogesterone-caproate-injection-information.

| 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. | 11/2021 |
| Q1 2023 annual review: no changes. | 11/2022 |
| Q3 2023: policy revised according to DHS revisions effective 07/10/2023. | 07/2023 |
| Q1 2024 annual review: no changes. | 11/2023 |
| Q1 2025 annual review: no changes. | 11/2024 |