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.084	**Effective Date: 01/05/2021** **Revision Date: 11/2024**
Policy Name: Androgenic 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 2025 annual review: no changes.

Name of Authorized Individual (Please type or print): **Craig A. Butler, MD MBA**	**Signature of Authorized Individual:**

Clinical Policy: Androgenic Agents

Reference Number: PHW.PDL.084
Effective Date: 01/01/2020
Last Review Date: 11/2024

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 PA Health & Wellness® that Androgenic Agents are **medically necessary** when the following criteria are met:

I. Requirements for Prior Authorization of Androgenic Agents

A. Prescriptions That Require Prior Authorization

All prescriptions for Androgenic Agents must be prior authorized.

B. Review of Documentation for Medical Necessity

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

1. Is prescribed the Androgenic Agent 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 prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Does not have a history of a contraindication to the prescribed medication; **AND**

4. For a diagnosis of hypogonadism, has clinical and laboratory findings (such as testosterone, luteinizing hormone [LH], follicle-stimulating hormone [FSH]) supporting the diagnosis; **AND**

5. For gender dysphoria, **both** of the following:
   a. Is prescribed the Androgenic Agent by or in consultation with an endocrinologist or medical provider with experience and/or training in transgender medicine,
   b. Is prescribed the Androgenic Agent in a manner consistent with the current World Professional Association for Transgender Health Standards of Care for the Health of Transgender and Gender Diverse People;

AND

6. For a non-preferred Androgenic Agent, has history of therapeutic failure, contraindication, or intolerance to the preferred Androgenic Agents approved or medically accepted for the beneficiary's diagnosis or indication. See the Preferred Drug List (PDL) for the list of preferred Androgenic Agents; **AND**

7. For therapeutic duplication, **one** of the following:
   a. Is being titrated to or tapered from a drug in the same class;
   b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;

AND

8. If a prescription for an Androgenic Agent 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 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 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 an Androgenic 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. **Approval Duration:**
   - **New request – 6 months**
   - **Renewal request – 12 months**

References

1. Snyder, P.J. Use of androgens and other hormones to enhance athletic performance, UpToDate. Accessed March 7, 2013.
2. Coleman E, Radix AE, Bouman WP, et al. Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. Int J Transgend Health. 2022 Sep 6;23(Suppl 1):S1-S259. doi: 10.1080/26895269.2022.2100644. PMID: 36238954; PMCID: PMC9553112.

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
Q1 2024 annual review: revised according to DHS revisions effective 01/08/2024	11/2023
Q1 2025 annual review: no changes.	11/2024