

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 whether the beneficiary:

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 are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Does not have 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 of or a contraindication or an 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 at: <https://papdl.com/preferred-drug-list>; **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;

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 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 beneficiary.

ANDROGENIC AGENTS PRIOR AUTHORIZATION FORM

<input type="checkbox"/> New request <input type="checkbox"/> Renewal request		# of pages: _____	Prescriber name:	
Name of office contact:			Specialty:	
Contact's phone number:			NPI:	State license #:
LTC facility contact/phone:			Street address:	
Beneficiary name:			Suite #:	City/state/zip:
Beneficiary ID#:	DOB:	Phone:	Fax:	

CLINICAL INFORMATION

Refer to <https://papdl.com/preferred-drug-list> for a list of preferred and non-preferred drugs in this class.

Drug requested:	Strength/concentration:	
Dosage form:	Package size:	
Dose/directions:	Quantity:	Refills:
Diagnosis (<i>submit documentation</i>):	Dx code (<i>required</i>):	
For a non-preferred Androgenic Agent: Does the beneficiary have a history of trial and failure of or contraindication or intolerance to the preferred drugs in this class approved or medically accepted for treatment of the beneficiary's condition? Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred drugs in this class.		<input type="checkbox"/> Yes – <i>Submit documentation.</i> <input type="checkbox"/> No
Is the requested medication prescribed for an indication that is supported by a drug reference, medical literature, and/or national treatment guidelines?	<input type="checkbox"/> Yes <input type="checkbox"/> No – <i>Submit medical literature supporting the use of the requested agent for the beneficiary's diagnosis.</i>	
<i>If being treated for hypogonadism:</i> Does the beneficiary have clinical and laboratory findings (such as testosterone, LH, FSH) that support the diagnosis?	<input type="checkbox"/> Yes – <i>Submit documentation.</i> <input type="checkbox"/> No	
<i>If being treated for gender dysphoria:</i> Is the requested medication prescribed by or in consultation with an endocrinologist or medical provider with experience and/or training in transgender medicine?	<input type="checkbox"/> Yes <i>Submit documentation of consultation if applicable.</i> <input type="checkbox"/> No	
<i>If being treated for gender dysphoria:</i> Is the requested medication prescribed in a manner consistent with current WPATH standards of care?	<input type="checkbox"/> Yes <i>Submit documentation.</i> <input type="checkbox"/> No	

PLEASE FAX COMPLETED FORM TO HIGHMARK WHOLECARE – PHARMACY DIVISION

Prescriber Signature:	Date:
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