Clinical Policy: Endocrine Agents: Androgens

Reference Number: OH.PHAR.PPA.48
Effective Date: 01.20
Last Review Date: 07.22
Line of Business: Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

ORAL AGENTS: ANDROGENS

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	METHYLTESTOSTERONE (generic of Android®, Methitest®, Testred®) JATENZO® (testosterone undecanoate)

INJECTABLE AGENTS: ANDROGENS

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	DEPO-TESTOSTERONE (testosterone cypionate) TESTOSTERONE CYPIONATE (generic of Depo-Testosterone TESTOSTERONE ENANTHATE (generic of Delatestryl) XYOSTED™ (testosterone enanthate)

TOPICAL AGENTS: ANDROGENS

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ANDRODERM® patch (testosterone) TESTOSTERONE gel 1% packet (generic of Androgel® 1% packet) TESTOSTERONE gel 1% pump (generic of Androgel® pump)	TESTOSTERONE gel 1.62% packet (generic of Androgel® 1.62% packet) NATESTO® nasal gel (testosterone) TESTOPEL pellet for implantation TESTOSTERONE gel (generic of Fortesta®, Testim®) TESTOSTERONE topical solution VOGELXO™ gel (testosterone)

FDA approved indication(s)

Androgen agents are indicated for androgen replacement therapy in patients with hypogonadism (primary and hypogonadotropic types).

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 Buckeye Health Plan, an affiliate of Centene Corporation® that Androgens are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

1. Prescribed indication is FDA-approved or supported by standard pharmacopeias;
2. Age ≥ 18 years;
3. Documentation of serum testosterone level < 300 ng/dL on at least 2 separate days within the last 6 months;
4. Failure of all preferred medications, each used for at least 90 days, unless member meets one of the following:
   a. Allergy to medications not requiring prior approval;
   b. Contraindication to or drug interaction with medications not requiring prior approval;
   c. History of unacceptable/toxic side effects to medications not requiring prior approval.
   **Prior authorization may be required for preferred medications.*

Approval Duration: 12 months

II. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PMN.53 for Medicaid or evidence of coverage documents.

III. Appendices/General Information

Appendix A: Abbreviation Key

FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Androderm® patch (testosterone)	Initiate with 1 patch of the 4 mg/day system (not two 2 mg/day systems) applied nightly to an area of dry, clean skin on the upper arms, thighs, back, or abdomen. The patch should be worn for 24 hours.	Dependent on indication for therapy
Testosterone gel 1% (Androgel® 1% packet)	Initially 5 g of 1% gel (containing 50 mg of testosterone and delivering 5 mg of testosterone systemically) applied once daily (preferably in the morning) to clean, dry, intact skin of the upper arms and/or abdomen.	Dependent on indication for therapy

Testosterone gel pump (Androgel®)	Initially, 40.5 mg of testosterone (2 pump actuations) applied once daily in the morning to clean, dry, intact skin of the shoulders and upper arms.	Dependent on indication for therapy

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed warnings

- Contraindications(s):
  - Male patients with prostate cancer or breast cancer
  - Females (Testim®)
  - Pregnancy
  - Sesame oil hypersensitivity (testosterone enanthate, Xyosted®)
  - Soybean, soy, or soya lecithin hypersensitivity (AndroGel®, Striant®)
- Boxed warning(s):
  - Accidental exposure (topical testosterone)
  - Hypertension (testosterone enanthate injection)

IV. Dosage and Administration

Drug	Dosing Regimen	Maximum Dose
Androgel 1.62%	Initially, 40.5 mg of testosterone (2 pump actuations or a single 40.5 mg packet) applied once daily in the morning to clean, dry, intact skin of the shoulders and upper arms.	Dependent on indication for therapy
Axiron gel	Initially, 60 mg (2 pump actuations) applied once daily (preferably in the morning) to clean, dry, intact skin of the axilla	Dependent on indication for therapy
Jatenzo (testosterone undecanoate)	237mg PO BID, once in the morning and once in the evening with food	396mg PO BID
Methyltestosterone (Android, Methitest, Testred)	10 to 50 mg PO per day	Dependent on indication for therapy
Natesto nasal gel	Administer 11 mg gel (2 pump actuations; 1 actuation per nostril) intranasally 3 times daily for a total of 33 mg/day [administer once in the morning, once in the afternoon, and once in the evening (6 to 8 hours apart, preferably at the same time each day)].	Dependent on indication for therapy

Striant	Apply one 30 mg buccal system twice daily to the gum region just above the incisor tooth, approximately every 12 hours. When applying a new system, the old system should be removed and discarded. Follow package instructions to ensure adhesion. The site of application should be rotated to alternate sides of the mouth with each application.	Dependent on indication for therapy
Testosterone cypionate oil (Depo-Testosterone)	Inject 50 to 400 mg intramuscularly once every 2 to 4 weeks	Dependent onindication for therapy
Testosterone enanthate oil (Delatestryl)	Inject 50 to 400 mg intramuscularly once every 2 to 4 weeks	Dependent on indication for therapy
Xyosted (testosterone enanthate solution)	Inject 75 mg subcutaneously in the abdominal region once weekly	Dependent on indication for therapy
Testosterone gel (Fortesta, Testim)	Fortesta: Initially, 40 mg (4 pump actuations) applied once daily in the morning to clean, dry, intact skin of the front and inner thighs. Testim: Initially, 5 grams gel (one tube containing 50 mg of testosterone and delivering 5 mg of testosterone systemically) applied once daily (preferably in the morning) to clean, dry, intact skin of the shoulders and/or upper arms.	Dependent on indication for therapy
Vogelxo	Initially, 50 mg applied once daily in the morning to the shoulder and/or upper arms.	Dependent on indication for therapy

For preferred agents please see Appendix B.

V. Product Availability

Drug	Availability
Androderm	Transdermal system: 2mg/24hr and 4mg/24hr
Androgel 1%	Metered dose pump topical gel: 1% Transdermal gel packets: 1%
Androgel 1.62%	Metered dose pump topical gel: 1.62% Transdermal gel packets: 1.62%

Axiron	Topical solution: 30mg/actuation
Jatenzo	Liquid filled oral capsules: 158mg, 198mg, 237mg
Methyltestosterone (Android, Methitest, Testred)	Android and Testred: 10 mg capsule Methitest: 10 mg tablet
Natesto	5.5mg/actuation nasal gel
Striant	30 mg buccal system
Testosterone (Androgel®)	Metered dose pump transdermal gel: 1% Metered dose pump transdermal gel: 1.62% Transdermal gel packets: 1% Transdermal gel packets: 1.62%
Testosterone cypionate oil (Depo-Testosterone)	Depo-Testosterone: 100 mg/mL and 200 mg/mL in oil for injection Testosterone cypionate: 100mg/mL, 200 mg/mL, 1000mg/10mL, and 2000mg/10mL in oil for injection
Testosterone enanthate oil (Delatestryl)	Delatestryl: 200mg/mL in oil for injection Testosterone enanthate: 200mg/mL and 1000mg/5mL in oil for injection
Xyosted (testosterone enanthate solution)	Auto-Injector solution for injection: 50mg/0.5mL, 75mg/0.5mL, and 100mg/0.5mL
Testosterone gel (Fortesta, Testim)	Fortesta formulations: 10mg/actuation transdermal Testim formulations: 1% topical gel
Vogelxo	Metered dose pump transdermal gel:12.5mg/actuation Transdermal gel: 50mg/5gm

VI. References

Refer to package inserts.

Reviews, Revisions, and Approvals	Date	Approval Date
Policy created	10/19	
Added Jatenzo (testosterone undecanoate) to list of non-preferred oral androgens	07.20	
Annual policy review. Added testosterone gel pump to the list of clinical PA required preferred topical agents.	07.21	

Annual review: Updated non-preferred products (removed Striant and Axiron (off market), added Testopel and testosterone topical solution)	07.22	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.