Title: Androgens and Anabolic Steroids

- Prime Therapeutics will review Prior Authorizations

Prior Authorization Form:

For information concerning Prior Authorization Prescription Drugs:
http://www.bcbsks.com/CustomerService/PrescriptionDrugs/prior_authorization.htm

Link to Drug List (Formulary):
http://www.bcbsks.com/CustomerService/PrescriptionDrugs/drug_list.htm

Professional
Original Effective Date: January 1, 2013
Revision Date(s): June 21, 2013;
August 15, 2014
Current Effective Date: August 15, 2014

Institutional
Original Effective Date: January 1, 2013
Revision Date(s): June 21, 2013;
August 15, 2014
Current Effective Date: August 15, 2014

State and Federal mandates and health plan member contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. To verify a member's benefits, contact Blue Cross and Blue Shield of Kansas Customer Service.

The BCBSKS Medical Policies contained herein are for informational purposes and apply only to members who have health insurance through BCBSKS or who are covered by a self-insured group plan administered by BCBSKS. Medical Policy for FEP members is subject to FEP medical policy which may differ from BCBSKS Medical Policy.

The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents of Blue Cross and Blue Shield of Kansas and are solely responsible for diagnosis, treatment and medical advice.

If your patient is covered under a different Blue Cross and Blue Shield plan, please refer to the Medical Policies of that plan.
DESCRIPTION
The intent of the Androgens and Anabolic Steroids Prior Authorization (PA) program is to appropriately select patients for therapy according to product labeling and/or clinical guidelines and/or clinical studies and according to dosing recommended in product labeling. The PA criteria will approve these products for the FDA approved indications and off label use that is medically necessary for certain indications (AIDS/HIV-associated wasting syndrome, Turner Syndrome). In addition, the program will encourage use of the preferred topical androgen product prior to a nonpreferred topical androgen product. Use of a nonpreferred topical androgen product will be evaluated if the prescriber indicates a history of a trial of or documented intolerance, FDA labeled contraindication, or hypersensitivity to a preferred topical androgen product. The program will approve only one of these products at a time. The program will approve topical and injectable androgens for doses within the FDA labeled dosage range. Determination of quantity limits takes into account the packaging of the products. Quantity limits apply only to the topical and injectable androgens, and will apply to preferred and nonpreferred topical products.

Target Drugs

<table>
<thead>
<tr>
<th>Preferred Topical Androgen Products</th>
<th>Nonpreferred Topical Androgen Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Androderm® (testosterone transdermal system)</td>
<td>• Axiron® (testosterone solution)</td>
</tr>
<tr>
<td>• AndroGel® (testosterone gel)</td>
<td>• Bio-T-Gel™ (testosterone gel)</td>
</tr>
<tr>
<td></td>
<td>• Fortesta™ (testosterone gel)</td>
</tr>
<tr>
<td></td>
<td>• Striant® (testosterone buccal system)</td>
</tr>
<tr>
<td></td>
<td>• Testim® (testosterone gel)</td>
</tr>
<tr>
<td></td>
<td>• First®-Testosterone (2% testosterone propionate in white petrolatum compounding kit)</td>
</tr>
<tr>
<td></td>
<td>• First®-Testosterone MC (2% testosterone propionate in moisturizing cream base compounding kit)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Injectable Androgen Products:</th>
<th>Oral Androgen Products:</th>
<th>Anabolic Steroid Products:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aveed™ (testosterone undecanoate)</td>
<td>Android® (methyltestosterone capsule)</td>
<td>Anadrol-50® (oxymetholone)</td>
</tr>
<tr>
<td>Delatestryl® (testosterone enanthate)</td>
<td>Androxy® (fluoxymesterone tablet)</td>
<td>danazol [Danocrine®]</td>
</tr>
<tr>
<td>Depo-Testosterone® (testosterone cypionate)</td>
<td>Methitest® (methyltestosterone tablet)</td>
<td>Oxandrin® (oxandrolone)</td>
</tr>
<tr>
<td>Testopel® (testosterone pellets)</td>
<td>Testred® (methyltestosterone capsule)</td>
<td></td>
</tr>
</tbody>
</table>

a - Brand drug has been discontinued by the manufacturer but may still be available.
b - Generic available and included in prior authorization and quantity limit programs.
c - Brand drug no longer available in the U.S. Only generic available.
d - Generic available and included in prior authorization program only.
e - FDA approved but not yet marketed; will be added to program when available.
### FDA Approved Indications and Dosage

<table>
<thead>
<tr>
<th>Topical Androgen Products</th>
<th>Indication</th>
<th>Dosage and Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Androderm®</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(testosterone transdermal system)</td>
<td></td>
<td><strong>Hypogonadism</strong></td>
</tr>
<tr>
<td>2 mg/day, 4 mg/day, transdermal system</td>
<td>For testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:</td>
<td><strong>2 mg/day and 4 mg/day system</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>-Primary hypogonadism</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(congenital or acquired):</td>
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<tr>
<td></td>
<td></td>
<td>testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-Hypogonadotrophic hypogonadism (congenital or acquired): idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation.</td>
</tr>
<tr>
<td><strong>AndroGel®</strong></td>
<td></td>
<td></td>
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<tr>
<td>(testosterone gel)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1% gel</td>
<td></td>
<td>1% gel:</td>
</tr>
<tr>
<td>25 mg/2.5 gm packet</td>
<td></td>
<td>-Initial dose is 50 mg of testosterone (4 pump actuations, two 25 mg packets, or one 50 mg packet) once daily in the morning.</td>
</tr>
<tr>
<td>50 mg/5 gm packet</td>
<td></td>
<td>-Dose may be increased to 75 mg and 100 mg daily based on measured serum testosterone levels.</td>
</tr>
<tr>
<td>75 gm pump</td>
<td></td>
<td>-If serum testosterone level exceeds normal range at 50 mg dose, therapy should be discontinued.</td>
</tr>
<tr>
<td>(12.5 mg testosterone / actuation; 60 actuations/pump)</td>
<td></td>
<td>1.62% gel:</td>
</tr>
<tr>
<td>1.62% gel</td>
<td></td>
<td>-40.5 mg of testosterone (2 pump actuations or 1 40.5 mg packet) applied topically once daily in the morning.</td>
</tr>
<tr>
<td>75 gm pump</td>
<td></td>
<td>-Dose may be adjusted between a minimum of 20.25 mg of testosterone (1 pump actuation or 1 packet) or maximum 81 mg of testosterone (4 pump actuations or 2 40.5 mg packets) based on measured serum testosterone levels.</td>
</tr>
<tr>
<td>(20.25 mg testosterone/actuation; 60 actuations/pump)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20.25 mg/1.25 gm packet</td>
<td></td>
<td></td>
</tr>
<tr>
<td>40.5 mg/2.5 gm packets</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Agent</td>
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<td>-----------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| Axiron® (testosterone soln) | For testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:  
- Primary hypogonadism  
(congenital or acquired): testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchietomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. | - Initial dose is 60 mg testosterone (2 pump actuations) applied once daily.  
- Dose of testosterone may be decreased to 30 mg (1 pump actuation) or increased to 90 mg (3 pump actuations) or 120 mg (4 pump actuations) based on the measured serum testosterone.  
- If serum testosterone concentration exceeds 1050 ng/dL at 30 mg, therapy should be discontinued. |
| Fortesta™ (testosterone gel) | Cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchietomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. | - Initial dose is 40 mg of testosterone (4 pump actuations) once daily in the morning.  
- Dose may be adjusted between a minimum of 10 mg of testosterone and a maximum of 70 mg of testosterone based on measured serum testosterone levels. |
| Striant® (testosterone buccal system) | Hypogonadotrophic hypogonadism  
(congenital or acquired): idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. | Usual dose is one buccal system (30 mg) to the gum region twice daily, morning and evening (about 12 hours apart). |
| Testim® (testosterone gel) | For testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:  
- Primary hypogonadism  
- Hypogonadotrophic hypogonadism  
(congenital or acquired) | 1% gel: - Initial dose is 50 mg testosterone (5 gm gel) once daily in the morning.  
- Dose may be increased to 75 mg and 100 mg daily based on measured serum testosterone levels.  
- If serum testosterone level exceeds normal range at 50 mg dose, therapy should be discontinued. |
<p>| First®-Testosterone | 2% testosterone propionate ointment in white petrolatum compounding kit | N/A |
| First®-Testosterone MC | 2% testosterone propionate in moisturizing cream base compounding kit | N/A |</p>
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<tr>
<th>Agent</th>
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</thead>
<tbody>
<tr>
<td><strong>Android®</strong>&lt;br&gt;(methyltestosterone)&lt;br&gt;10 mg capsule</td>
<td>Males:&lt;br&gt;-Androgen replacement therapy, including erectile dysfunction (ED) (impotence) or hypogonadism&lt;br&gt;-Androgen replacement therapy related to cryptorchidism&lt;br&gt;-Delayed puberty in males</td>
<td>Males:&lt;br&gt;-Androgen replacement therapy, including ED (impotence) or hypogonadism- 10 mg to 50 mg/day&lt;br&gt;-Androgen replacement therapy related to cryptorchidism: 10 mg 3 times daily&lt;br&gt;-Delayed puberty (adolescents only)- 5 mg to 25 mg/day for a limited period, usually for 4 to 6 months</td>
</tr>
<tr>
<td><strong>Methitest®</strong>&lt;br&gt;(methyltestosterone)&lt;br&gt;10 mg tablet</td>
<td>Males:&lt;br&gt;-Androgen replacement therapy related to cryptorchidism&lt;br&gt;-Delayed puberty in males&lt;br&gt;Females:&lt;br&gt;Palliative treatment of breast cancer in women</td>
<td>Males:&lt;br&gt;-Androgen replacement therapy, including ED (impotence) or hypogonadism- 10 mg to 50 mg/day&lt;br&gt;-Androgen replacement therapy related to cryptorchidism: 10 mg 3 times daily&lt;br&gt;-Delayed puberty (adolescents only)- 5 mg to 25 mg/day for a limited period, usually for 4 to 6 months&lt;br&gt;Females:&lt;br&gt;-50 mg once daily up to four times/day&lt;br&gt;-If suitable response within 2-4 weeks, decrease to 25 mg two times daily</td>
</tr>
<tr>
<td><strong>Testred®</strong>&lt;br&gt;(methyltestosterone)&lt;br&gt;10 mg capsule</td>
<td>Males:&lt;br&gt;-Androgen replacement therapy&lt;br&gt;-Treatment of delayed puberty in males&lt;br&gt;Females:&lt;br&gt;Palliative treatment of breast cancer in women</td>
<td>Males:&lt;br&gt;-Androgen replacement therapy, including ED (impotence) or hypogonadism- 10 mg to 50 mg/day&lt;br&gt;-Androgen replacement therapy related to cryptorchidism: 10 mg 3 times daily&lt;br&gt;-Delayed puberty (adolescents only)- 5 mg to 25 mg/day for a limited period, usually for 4 to 6 months&lt;br&gt;Females:&lt;br&gt;-50 mg once daily up to four times/day&lt;br&gt;-If suitable response within 2-4 weeks, decrease to 25 mg two times daily</td>
</tr>
<tr>
<td><strong>Androxy®</strong>&lt;br&gt;(fluoxymesterone)&lt;br&gt;10 mg tablet</td>
<td>Males:&lt;br&gt;-Androgen replacement therapy in male hypogonadism&lt;br&gt;-Treatment of delayed puberty in males&lt;br&gt;Females:&lt;br&gt;Inoperable breast cancer</td>
<td>Males:&lt;br&gt;-Androgen replacement therapy, including ED (impotence) or hypogonadism- 10 mg to 50 mg/day&lt;br&gt;-Androgen replacement therapy related to cryptorchidism: 10 mg 3 times daily&lt;br&gt;-Delayed puberty (adolescents only)- 5 mg to 25 mg/day for a limited period, usually for 4 to 6 months&lt;br&gt;Females:&lt;br&gt;-50 mg once daily up to four times/day&lt;br&gt;-If suitable response within 2-4 weeks, decrease to 25 mg two times daily</td>
</tr>
<tr>
<td><strong>Anadrol-50®</strong>&lt;br&gt;(oxymetholone)&lt;br&gt;50 mg tablet</td>
<td>Treatment of anemias caused by deficient red cell production. Acquired aplastic anemia, congenital aplastic anemia, myelofibrosis and the hypoplastic anemias due to the administration of myelotoxic drugs often respond</td>
<td>Adults and children&lt;br&gt;-1 to 5 mg/kg body weight per day.&lt;br&gt;-Usual effective dose is 1 to 2 mg/kg/day; higher doses may be required, dose should be individualized.&lt;br&gt;-Response is not often immediate; minimum trial of 3 to 6 months should be given&lt;br&gt;-Following remission, some patients may be maintained without the drugs; others may be maintained on an established lower daily dosage&lt;br&gt;-A continued maintenance dose is usually necessary in patients with congenital aplastic anemia</td>
</tr>
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</table>
### Oral Androgen and Anabolic Products (con’t)

<table>
<thead>
<tr>
<th>Agent</th>
<th>Indication</th>
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</table>
| danazol [Danocrine®]a | - Fibrocystic breast disease  
                   - Angioedema prophylaxis in patients with hereditary angioedema  
                   - Endometriosis amenable to hormone management  | - Fibrocystic breast disease: 100 to 400 mg/day in 2 divided doses. Although symptoms may be relieved, and even eliminated in 3 months, up to 6 months of uninterrupted therapy may be required to eliminate nodularity.  
                   - Angioedema prophylaxis: Initial 200 mg two to three times daily. If a favorable response achieved, dose may be reduced by half at intervals of 1-3 months. If unfavorable response (attack of angioedema during treatment), dose may be increased by up to 200 mg/day.  
                   - Endometriosis: In moderate/severe disease or patients infertile due to endometriosis: starting dose of 800 mg given in two divided doses. Gradual downward titration to dose sufficient to maintain amenorrhea may be considered. In mild disease: starting dose of 200 mg to 400 mg given in two divided doses; adjust depending on patient response. Continue therapy for 3 to 6 months, may be extended to 9 months if necessary. |
| 50 mg, 100 mg, 200 mg capsule |                                                                          |                                                                                          |
| Oxandrin® (oxandrolone)b | - Adjunctive therapy to promote weight gain after weight loss following extensive surgery, chronic infections, severe trauma, and in some patients without definite pathophysiologic reasons who fail to gain or to maintain normal weight, to offset the protein catabolism associated with prolonged administration of corticosteroids, and for the relief of the bone pain frequently accompanying osteoporosis | Adults:  
                   - Daily adult dosage is 2.5 mg to 20 mg given in 2 to 4 divided doses.  
                   - Desired response may be achieved with as little as 2.5 mg or as much as 20 mg daily.  
                   - A course of therapy of 2 to 4 weeks is usually adequate. This may be repeated intermittently as indicated.  
                   - Children: Total daily dosage is ≤0.1 mg/kg body weight or ≤0.045 mg per pound of body weight. This may be repeated intermittently as indicated  
                   - Geriatric: 5 mg twice daily |
<p>| 2.5 mg, 10 mg tablet |                                                                          |                                                                                          |</p>
<table>
<thead>
<tr>
<th>Agent</th>
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<th>Dosage and Administration</th>
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</thead>
</table>
| Delatestryl® (testosterone enanthate)<sup>b,c</sup> | Males: For replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone:  
- Erectile dysfunction  
- Primary hypogonadism (congenital or acquired): testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, or orchidectomy  
- Hypogonadotropic hypogonadism (congenital or acquired): idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. Prior to puberty, androgen replacement therapy needed during adolescent years for development of secondary sexual characteristics. Prolonged androgen treatment required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty  
- Delayed puberty  

Females:  
Palliative treatment of breast cancer that is inoperable in women | Males:  
- Erectile dysfunction: 50 mg to 400 mg IM every 2 to 4 weeks  
- Hypogonadism  
  - Adult males: 50 mg to 400 mg IM every 2 to 4 weeks  
  - Children (initiation of pubertal growth): 40 mg to 50 mg/m² IM monthly until growth rate falls to prepubertal levels.  
    - Terminal growth phase: 100 mg/m² IM monthly until growth ceases  
    - Maintenance of virilization: 100 mg/m² IM twice monthly  

- Delayed puberty: 50 mg to 200 mg IM every 2 to 4 weeks for a limited duration, for example, 4 to 6 months or 40 mg to 50 mg/m²/dose IM monthly for 6 months  

Females:  
Palliation of inoperable breast cancer: 200 mg to 400 mg IM every 2 to 4 weeks |
<table>
<thead>
<tr>
<th>Agent</th>
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<th>Dosage and Administration</th>
</tr>
</thead>
</table>
| **Testopel®**<br>(testosterone pellets)<br>75 mg | - Primary hypogonadism (congenital or acquired): testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome; or orchiectomy<br>- Hypogonadotropic hypogonadism (congenital or acquired): idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation.<br>- Delayed puberty in males | - Hypogonadism (adult males and children): 150 mg to 450 mg (2-6 pellets) inserted subcutaneously by a healthcare professional every 3 to 6 months  
- Dosage is based on the minimal daily requirements of testosterone propionate determined by a gradual reduction of the amount administered parenterally  
  - For every 75 mg/week of testosterone propionate, 150 mg (2 pellets) should be implanted every 3—6 months  
- Delayed puberty (adolescents only): 150 mg to 450 mg (2-6 pellets) inserted subcutaneously by a healthcare professional every 3 to 6 months, although the lower end of the dosing range is typically sufficient  
  - Treatment is usually only required for 4—6 months  
  - Dosage is based on the minimal daily requirements of testosterone propionate determined by a gradual reduction of the amount administered parenterally  
  
For every 75 mg/week of testosterone propionate, 150 mg (2 pellets) should be implanted every 3—6 months. |
| **Aveed™**<br>(testosterone undecanoate)<br>250 mg/mL | - Primary hypogonadism (congenital or acquired): testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome; or orchiectomy | The recommended dose of Aveed is 3 mL (750 mg) injected intramuscularly, followed by 3 mL (750 mg) injected after 4 weeks, then 3 mL (750 mg) injected every 10 weeks thereafter. |

*a* - Brand drug no longer available; available as generic only  
*b* - Generic available  
*c* - Brand drug has been discontinued by the manufacturer but may still be available.
<table>
<thead>
<tr>
<th>Brand (generic)</th>
<th>Quantity Per Day Limit (or as noted)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Topical Androgen Products</strong></td>
<td></td>
</tr>
<tr>
<td>Androderm® (testosterone transdermal system)</td>
<td></td>
</tr>
<tr>
<td>2 mg/day transdermal system</td>
<td>1 patch</td>
</tr>
<tr>
<td>4 mg/day transdermal system</td>
<td>1 patch</td>
</tr>
<tr>
<td>AndroGel® (testosterone gel)</td>
<td></td>
</tr>
<tr>
<td>1% gel, 25 mg/2.5 gm packet</td>
<td>2 packets</td>
</tr>
<tr>
<td>1% gel, 50 mg/5 gm packet</td>
<td>2 packets</td>
</tr>
<tr>
<td>1% gel, 75 gm pump (1.25 gm/actuation; 60 actuations/pump)</td>
<td>10 gm/day (4 pumps/30 days)</td>
</tr>
<tr>
<td>1% gel, 2 x 75 gm pump (1.25 gm/actuation; 60 actuations/pump)</td>
<td>10 gm/day (4 pumps/30 days)</td>
</tr>
<tr>
<td>1.62% gel, 20.25 mg/1.25 gm packet</td>
<td>1 packet</td>
</tr>
<tr>
<td>1.62% gel, 40.5 mg/2.5 gm packet</td>
<td>2 packets</td>
</tr>
<tr>
<td>1.62% gel, 75 gm pump (1.25 gm/actuation; 60 actuations/pump)</td>
<td>5 gm/day (2 pumps/30 days)</td>
</tr>
<tr>
<td>Axiron® (testosterone solution)</td>
<td></td>
</tr>
<tr>
<td>30 mg/1.5 mL, 90 mL pump</td>
<td>120 mg/day (2 pumps/30 days)</td>
</tr>
<tr>
<td>Bio-T-Gel™ (testosterone gel)</td>
<td></td>
</tr>
<tr>
<td>1% gel, 25 mg/2.5 gm packet</td>
<td>2 packets</td>
</tr>
<tr>
<td>1% gel, 50 mg/5 gm packet</td>
<td>2 packets</td>
</tr>
<tr>
<td>Fortesta™ (testosterone gel)</td>
<td></td>
</tr>
<tr>
<td>2% gel, 60 gm pump</td>
<td>70 mg/day (2 pumps/30 days)</td>
</tr>
<tr>
<td>Striant® (testosterone buccal system)</td>
<td></td>
</tr>
<tr>
<td>30 mg buccal system</td>
<td>2 systems</td>
</tr>
<tr>
<td>Testim® (testosterone gel)</td>
<td></td>
</tr>
<tr>
<td>1% gel, 5 gm tube</td>
<td>2 tubes</td>
</tr>
<tr>
<td><strong>Injectable Androgen Products</strong></td>
<td></td>
</tr>
<tr>
<td>Aveed™ (testosterone undecanoate)</td>
<td></td>
</tr>
<tr>
<td>250 mg/mL, 3 mL vial</td>
<td>1 vial/28 days</td>
</tr>
<tr>
<td>Delatestryl® (testosterone enanthate)(^a, b)</td>
<td></td>
</tr>
<tr>
<td>200 mg/mL, 5 mL multiple dose vial</td>
<td>1 vial/28 days</td>
</tr>
<tr>
<td>Depo-Testosterone® (testosterone cypionate)(^b)</td>
<td></td>
</tr>
<tr>
<td>100 mg/mL, 10 mL multiple dose vial</td>
<td>1 vial/28 days</td>
</tr>
<tr>
<td>200 mg/mL, 1 mL vial</td>
<td>4 vials/28 days</td>
</tr>
<tr>
<td>200 mg/mL, 10 mL multiple dose vial</td>
<td>1 vial/28 days</td>
</tr>
<tr>
<td>Testopel® (testosterone pellets)</td>
<td></td>
</tr>
<tr>
<td>75 mg</td>
<td>6 pellets/90 days</td>
</tr>
</tbody>
</table>

\(^a\) - Brand drug has been discontinued by the manufacturer but may still be available

\(^b\) - Generic available and included in prior authorization and quantity limit programs
### FDA Labeled Contraindications

<table>
<thead>
<tr>
<th>Topical Androgen Products</th>
<th>Contraindications</th>
</tr>
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</table>
| Androderm                 | 1. Men with carcinoma of the breast or known or suspected carcinoma of the prostate  
                            | 2. Women who are or may become pregnant, or who are breastfeeding |
| Androgel                  |                   |
| Axiron                    |                   |
| Bio-T-Gel                 |                   |
| Fortesta                  |                   |
| Striant                   |                   |
| Testim                    |                   |

<table>
<thead>
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<th>Injectable Androgen Products</th>
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</table>
| Aveed (testosterone undecanoate) | 1. Men with carcinoma of the breast or known or suspected carcinoma of the prostate  
                                      | 2. Women who are or may become pregnant or are breastfeeding  
                                      | 3. Hypersensitivity to Aveed or any of its ingredients (testosterone undecanoate, refined castor oil, benzyl benzoate) |
| Delatestryl (testosterone enanthate) | 1. Men with carcinoma of the breast or known or suspected carcinoma of the prostate  
                                          | 2. Women who are or may become pregnant |
| Testopel                    |                   |
| Depo-Testosterone (testosterone cypionate) | 1. Men with carcinoma of the breast or known or suspected carcinoma of the prostate  
                                              | 2. Women who are or may become pregnant  
                                              | 3. Patients with serious cardiac, hepatic or renal disease  
                                              | Severe liver disease: Child Pugh Grade III-IV (or refractory)  
                                              | Severe renal disease: Stage 4 Severe CKD (GFR=15-29 mL/min) or Stage 5 End Stage CKD (GFR <15 mL/min) |

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<thead>
<tr>
<th>Oral Androgen Products</th>
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<tbody>
<tr>
<td>Android</td>
<td>1. Male patients with prostate cancer or breast cancer</td>
</tr>
<tr>
<td>Methitest</td>
<td>2. Pregnant women</td>
</tr>
<tr>
<td>Testred</td>
<td></td>
</tr>
</tbody>
</table>
| Androxy                | 1. Known or suspected prostate cancer  
                            | 2. Men with breast cancer  
                            | 3. Women who are or may become pregnant |

<table>
<thead>
<tr>
<th>Anabolic Steroid Products</th>
<th>Contraindications</th>
</tr>
</thead>
</table>
| Anadrol-50               | 1. Carcinoma of the prostate or breast in male patients  
                            | 2. Carcinoma of the breast in females with hypercalcemia (normal calcium blood values range from 8.5 to 10.2 mg/dL and may vary slightly among different laboratories); androgenic anabolic steroids may stimulate osteolytic resorption of bones  
                            | 3. Women who are or may become pregnant  
                            | 4. Nephrosis or the nephrotic phase of nephritis  
                            | 5. Severe hepatic dysfunction: Child Pugh Grade III-IV (or refractory)  
                            | 6. Severe hepatic disease: Child Pugh Grade III-IV (or refractory)  
                            | 7. Severe renal disease, including renal failure: Stage 4 Severe CKD (GFR=15-29 mL/min) or Stage 5 End Stage CKD (GFR <15 mL/min) |
| danazol                 | 1. Breast-feeding  
                            | 2. Pregnancy  
                            | 3. Porphyria  
                            | 4. Vaginal bleeding  
                            | 5. Cardiac disease  
                            | 6. Severe hepatic disease: Child Pugh Grade III-IV (or refractory)  
                            | 7. Severe renal disease, including renal failure: Stage 4 Severe CKD (GFR=15-29 mL/min) or Stage 5 End Stage CKD (GFR <15 mL/min) |
Anabolic Steroid Products (con't)

<table>
<thead>
<tr>
<th>Agent</th>
<th>Contraindications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxandrin</td>
<td>1. Known / suspected carcinoma of prostate or male breast</td>
</tr>
<tr>
<td>(oxandrolone)</td>
<td>2. Carcinoma of the breast in females with hypercalcemia (normal calcium blood values range from 8.5 to 10.2 mg/dL and may vary slightly among different laboratories); androgenic anabolic steroids may stimulate osteolytic bone resorption</td>
</tr>
<tr>
<td></td>
<td>3. Pregnancy</td>
</tr>
<tr>
<td></td>
<td>4. Nephrosis, the nephrotic phase of nephritis</td>
</tr>
<tr>
<td></td>
<td>5. Hypercalcemia (normal calcium blood values range from 8.5 to 10.2 mg/dL and may vary slightly among different laboratories)</td>
</tr>
</tbody>
</table>

POLICY

Prior Authorization Criteria for Approval

A. **Androderm, AndroGel, Axiron, Bio-T-Gel, Fortesta, Striant, Testim, First-Testosterone, or First-Testosterone MC** will be approved when **ALL** of the following are met:

1. The patient has **ONE** of the following diagnoses:
   a. Patient is a male or female with AIDS/HIV-associated wasting syndrome, defined as unexplained involuntary weight loss (≥10% baseline body weight) with obvious wasting OR body mass index <18.5 kg/m² AND all other causes of weight loss have been ruled out **OR**
   b. Patient is a male with primary or secondary (hypogonadotropic) hypogonadism **AND**

2. Males only: The patient has a measured pretreatment or current total serum testosterone level that is below the testing laboratory’s lower limit of the normal range or is less than 300 ng/dL OR a free serum testosterone level that is below the testing laboratory’s lower limit of the normal range **AND**

3. The patient does **NOT** have any FDA labeled contraindication(s) **AND**

4. **ONE** of the following:
   a. The requested agent is a preferred topical androgen product **OR**
   b. **ONE** of the following:
      1) The patient’s medication history indicates use of a preferred topical androgen **OR**
      2) The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a preferred topical androgen **AND**
5. ONE of the following:
   a. The patient will be receiving only one androgen or anabolic agent
   OR
   b. The prescriber has submitted documentation in support of therapy with
      more than one agent
   AND

6. ONE of the following:
   a. The quantity requested is within the set quantity limit
   OR
   b. The quantity (dose) requested is within FDA approved labeling and the
      prescribed dose cannot be achieved using a lesser quantity of a higher
      strength
   OR
   c. The quantity (dose) requested is greater than the maximum dose
      recommended in FDA labeling and prescriber has submitted
      documentation in support of therapy with a higher dose for the intended
      diagnosis

Length of Approval: 12 months

B. **Delatestryl** (**testosterone enanthate**) or **Depo-Testosterone** (**testosterone cypionate**) will be approved when **ALL** of the following are met:

1. The patient has ONE of the following diagnoses:
   a. Patient is a male with AIDS/HIV-associated wasting syndrome, defined as
      unexplained involuntary weight loss (>10% baseline body weight) with
      obvious wasting OR body mass index <18.5 kg/m² AND all other causes
      of weight loss have been ruled out
   OR
   b. Patient is a male with erectile dysfunction
   OR
   c. Patient is a female with metastatic/inoperable breast cancer
   OR
   d. Patient is a male with primary or secondary (hypogonadotropic)
      hypogonadism
   OR
   e. Patient is an adolescent male with delayed puberty
   AND

2. Males only: The patient has a measured pretreatment or current total serum
   testosterone level that is below the testing laboratory’s lower limit of the
   normal range or is less than 300 ng/dL OR a free serum testosterone level that
   is below the testing laboratory’s lower limit of the normal range
   AND

3. The patient does NOT have any FDA labeled contraindication(s)
   AND
4. ONE of the following:
   a. The patient will be receiving only one androgen or anabolic agent
   OR
   b. The prescriber has submitted documentation in support of therapy with more than one agent

      AND

5. ONE of the following:
   a. The quantity requested is within the set quantity limit
   OR
   b. The quantity (dose) requested is within FDA approved labeling and the prescribed dose cannot be achieved using a lesser quantity of a higher strength
   OR
   c. The quantity (dose) requested is greater than the maximum dose recommended in FDA labeling and prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis

Length of Approval: 6 months (delayed puberty only)
12 months (all other indications)

C. Aveed or Testopel will be approved when ALL of the following are met:
1. The patient has ONE of the following diagnoses:
   a. Patient is a male with primary or secondary (hypogonadotropic) hypogonadism
   OR
   b. Patient is an adolescent male with delayed puberty

      AND

2. The patient has a measured pretreatment or current total serum testosterone level that is below the testing laboratory’s lower limit of the normal range or is less than 300 ng/dL OR a free serum testosterone level that is below the testing laboratory’s lower limit of the normal range

      AND

3. The patient does NOT have any FDA labeled contraindication(s)

      AND

4. ONE of the following:
   a. The patient will be receiving only one androgen or anabolic agent
   OR
   b. The prescriber has submitted documentation in support of therapy with more than one agent

      AND

5. ONE of the following:
   a. The quantity requested is within the set quantity limit
   OR
b. The quantity (dose) requested is within FDA approved labeling and the prescribed dose cannot be achieved using a lesser quantity of a higher strength
   OR

c. The quantity (dose) requested is greater than the maximum dose recommended in FDA labeling and the prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis

**Length of Approval:** 6 months (delayed puberty only)
12 months (all other indications)

### D. Android, Androxy, Methitest, Testred

**Android, Androxy, Methitest, Testred** will be approved when **ALL** of the following are met:

1. The patient has **ONE** of the following diagnoses:
   a. Patient is a male with erectile dysfunction
   OR
   b. Patient is a male with cryptorchidism
   OR
   c. Patient is a male with hypogonadism
   OR
   d. Patient is an adolescent male with delayed puberty
   OR
   e. Patient is a female with metastatic/inoperable breast cancer
   **AND**

2. **Males only:** The patient has a measured pretreatment or current total serum testosterone level that is below the testing laboratory’s lower limit of the normal range or is less than 300 ng/dL OR a free serum testosterone level that is below the testing laboratory’s lower limit of the normal range
   **AND**

3. The patient does **NOT** have any FDA labeled contraindication(s)
   **AND**

4. **ONE** of the following:
   a. The patient will be receiving only one androgen or anabolic agent
   **OR**
   b. The prescriber has submitted documentation in support of therapy with more than one agent

**Length of Approval:** 6 months (delayed puberty only)
12 months (all other indications)
E. **Anadrol-50** will be approved when **ALL** of the following are met:
   1. The patient has **ONE** of the following diagnoses:
      a. Patient has anemia caused by deficient red cell production, including acquired aplastic anemia, congenital aplastic anemia, myelofibrosis and the hypoplastic anemias due to the administration of myelotoxic drugs **OR**
      b. Patient has anemia associated with chronic renal failure AND **ONE** of the following:
         1) The patient’s medication history indicates previous use of an erythropoiesis-stimulating agent **OR**
         2) The patient has documented intolerance, FDA labeled contraindication or hypersensitivity to an erythropoiesis-stimulating agent
   AND
   2. The patient has a hematocrit (Hct) value <30%
   AND
   3. The patient does **NOT** have any FDA labeled contraindication(s)
   AND
   4. **ONE** of the following:
      a. The patient will be receiving only one androgen or anabolic agent **OR**
      b. The prescriber has submitted documentation in support of therapy with more than one agent

**Length of Approval**: 12 months

F. **Danazol** will be approved when **ALL** of the following are met:
   1. The patient has **ONE** of the following diagnoses:
      a. Patient has fibrocystic breast disease **OR**
      b. Patient has hereditary angioedema **OR**
      c. Patient has endometriosis
   AND
   2. The patient does **NOT** have any FDA labeled contraindication(s)
   AND
   3. **ONE** of the following:
      a. The patient will be receiving only one androgen or anabolic agent **OR**
      b. The prescriber has submitted documentation in support of therapy with more than one agent

**Length of Approval**: 12 months
G. **Oxandrin (oxandroloine)** will be approved when **ALL** of the following are met:

1. The patient has **ONE** of the following diagnoses:
   a. Patient is a male or female with AIDS/HIV-associated wasting syndrome (defined as unexplained involuntary weight loss >10% baseline body weight with obvious wasting or body mass index <18.5 kg/m²) AND all other causes of weight loss have been ruled out **OR**
   b. Patient is a female child or adolescent with Turner syndrome AND is currently receiving growth hormone **OR**
   c. Patient has weight loss following extensive surgery, chronic infections, or severe trauma **OR**
   d. Patient has chronic pain from osteoporosis **OR**
   f. Patient is on long-term administration of oral or injectable corticosteroids **AND**

2. The patient does **NOT** have any FDA labeled contraindication(s) **AND**

3. **ONE** of the following:
   a. The patient will be receiving only one androgen or anabolic agent **OR**
   b. The prescriber has submitted documentation in support of therapy with more than one agent

**Length of Approval:** 12 months

**RATIONALE**

**Efficacy**
Testosterone, the primary androgen produced in the testes, is responsible for a variety of physiologic functions that include: the normal growth and development of male sex organs, maintenance of secondary sex characteristics, stimulating and maintaining sexual function in men, the growth spurt of that seen in adolescence, increasing lean body mass and weight, increasing the formation of clotting factors in the liver, and stimulating the production of red blood cells. Therapeutically, testosterone is used in the management of hypogonadism (congenital or acquired). Testosterone is also the most effective exogenous androgen for the palliative treatment of carcinoma of the breast in postmenopausal women. Anabolic steroids possess the same pharmacologic functions as that of the androgens; however, have a much higher ratio of nitrogen-containing properties to increase muscle mass.11

According to the World Health Organization (WHO) Guidelines for the Use of Androgens in Men (1992), the ideal testosterone replacement therapy should offer safety, efficacy, convenience, a good release profile, dosing flexibility, and effective normalization of testosterone levels.12
The Endocrine Society Clinical Practice Guidelines (2011): Testosterone Therapy in Adult Men with Androgen Deficiency Syndromes recommends the following:\(^13\):

We suggest initiating testosterone therapy with any of the following regimens, chosen on the basis of the patient’s preference, consideration of pharmacokinetics, treatment burden, and cost.

- 75–100 mg of testosterone enanthate or cypionate administered intramuscularly (IM) weekly, or 150–200 mg administered every 2 weeks.
- One or two 5-mg nongenital, testosterone patches applied nightly over the skin of the back, thigh or upper arm, away from pressure areas.
- 5–10 g of a 1% testosterone gel applied daily over a covered area of nongenital skin (patients should wash hands after application).
- 30 mg of a bioadhesive buccal testosterone tablet applied to buccal mucosa every 12 hours.

The International Society of Andrology (ISA), the International Society for the Study of the Aging Male (ISSAM), the European Association of Urology (EAU), the European Academy of Andrology (EAA), and the American Society of Andrology (ASA) consensus statement on "Investigation, Treatment, and Monitoring of Late-Onset Hypogonadism" includes the following recommendations:\(^14\):

- Currently available intramuscular, subdermal, transdermal, oral, and buccal preparations of testosterone are safe and effective. The treating physician should have sufficient knowledge and adequate understanding of the pharmacokinetics as well as of the advantages and drawbacks of each preparation. The selection of the preparation should be a joint decision of an informed patient and physician.

**Off Label Use**

Androgens and anabolic steroids have been studied for use in AIDS/HIV-associated wasting syndrome and Turner syndrome. Clinical studies support the use of the following agents in men for AIDS/HIV-associated wasting syndrome: testosterone transdermal system\(^18\), testosterone enanthate\(^19,20,23\), and oxandrolone.\(^21,22\). The use of topical testosterone to treat AIDS wasting in women is supported by several studies.\(^32,33\) Oxandrolone was studied in both male and female pediatric patients.\(^22\) Dosing for AIDS/HIV-associated wasting is as follows:

- **testosterone transdermal system:** Two 2.5 mg systems applied every 24 hours
- **oxandrolone:**
  - **Adults:** 5 mg to 15 mg daily
  - **Adolescents and Children:** 0.1 mg/kg/day for 12 weeks
- **testosterone enanthate:** 300 mg IM every 3 weeks for 6 months or 200 mg IM weekly

The Turner Syndrome Consensus Study Group, sponsored by the National Institutes of Health’s National Institute of Child Health and Human Development, recommends oxandrolone for treatment of Turner syndrome, when used in conjunction with growth hormone (GH).\(^17\) Recommended dose of oxandrolone is 0.05 mg/kg*d or less in conjunction with growth hormone only. Therapy may be continued until a satisfactory height has been attained or until little growth potential remains (bone age \(\geq 14\) yr and growth velocity <2 cm/yr).

The National Kidney Foundation’s Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guidelines and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease have a strong recommendation against the use of androgens as adjuvant to erythropoiesis-stimulating agent (ESA) treatment in anemia patients with chronic kidney disease.\(^24\) The current guideline has serious safety concerns and states evidence for androgens’ efficacy is low quality.
Before the availability of epoetin therapy, androgens were used regularly in the treatment of anemia in dialysis patients.

The DMD (Duchenne muscular dystrophy) Care Considerations Working Group guidelines recommend glucocorticoids as first-line treatment for Duchenne muscular dystrophy. Glucocorticoids are the only medication currently available that slow the decline in muscle strength and function in DMD, which in turn reduces the risk of scoliosis and stabilizes pulmonary function. Oxandrolone is not considered necessary or appropriate, either with or without glucocorticoid therapy.25

The American Congress of Obstetricians and Gynecologists (ACOG) guidelines for vulvar skin disorders recommend a high potency topical steroid such as clobetasol propionate for treatment of lichen sclerosus. Topical testosterone has shown inconsistent results in trials.26 The British Association of Dermatologists’ guidelines state that “there appears to be no evidence base for the use of topical testosterone” for treatment of female anogenital lichen sclerosus.31 Testosterone propionate has been used for decreased libido and vulva atrophy/dystrophy; such indications are not FDA approved. The Endocrine Society recommends against the generalized use of testosterone by women because the indications are inadequate and evidence of long-term studies is lacking.28

Aveed: Prescribing information carries a boxed warning:34
- Serious Pulmonary Oil Microembolism (POME) reactions, involving urge to cough, dyspnea, throat tightening, chest pain, dizziness, and syncope; and episodes of anaphylaxis, including life-threatening reactions, have been reported to occur during or immediately after the administration of testosterone undecanoate injection. These reactions can occur after any injection of testosterone undecanoate during the course of therapy, including after the first dose
- Following each injection of Aveed, observe patients in the healthcare setting for 30 minutes in order to provide appropriate medical treatment in the event of serious POME reactions or anaphylaxis
- Because of the risks of serious POME reactions and anaphylaxis, Aveed is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Aveed REMS Program

Safety
Androgens and anabolic steroids are associated with cardiomyopathy, increased low density lipoprotein (LDL), decreased high density lipoprotein (HDL), hepatotoxicity (including hepatic neoplasms), hypertrophy of the prostate and anabolic-androgenic steroids-induced hypogonadism.15 Testosterone treatment in men aged 65 years and older who have limitations in mobility was associated with an increased risk for cardiovascular events, including myocardial infarction and hypertension, according to a study published by Basaria, et al.16 Anabolic steroids are mainly abused by males and athletes to increase muscle mass and improve athletic performance.

Since the possible development of an adverse event during treatment (especially elevated hematocrit or prostate carcinoma) requires rapid discontinuation of testosterone substitution, short-acting preparations may be preferred over long-acting depot preparations in the initial treatment of patients with late onset hypogonadism.14
Boxed Warnings
Testosterone gel and solution: Virilization has been reported in children who were secondarily exposed to testosterone gel. ²⁻⁵,⁷

Oxandrolone and oxymetholone: Peliosis hepatis, a condition in which liver and sometimes splenic tissue is replaced with blood-filled cysts, and liver cell tumors have been reported. The cysts and tumors are often not recognized until life-threatening liver failure or intra-abdominal hemorrhage develops. Blood lipid changes such as decreased HDL and increased LDL that are known to be associated with increased risk of atherosclerosis are seen in patients treated with androgens and anabolic steroids. ⁸⁻⁹

Danazol: Do not use in patients with severe hepatic disease. Danazol use can cause hepatic dysfunction including cholestatic jaundice, peliosis of the liver, and benign hepatic adenoma. Peliosis and adenoma may not be apparent until patients present with life-threatening intra-abdominal hemorrhage. Regular liver function tests (LFTs) should be carried out in all patients.¹¹

CODING
The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

<table>
<thead>
<tr>
<th>HCPCS</th>
<th>Description</th>
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<tbody>
<tr>
<td>J1070</td>
<td>Injection, testosterone cypionate, up to 100 mg (Use this code for Depo-Testosterone cypionate)</td>
</tr>
<tr>
<td>J1080</td>
<td>Injection, testosterone cypionate, 1cc, 200 mg (Use this code for Depo-Testosterone cypionate)</td>
</tr>
<tr>
<td>J3120</td>
<td>Injection, testosterone enanthate, up to 100 mg (Use this code for Delatestryl)</td>
</tr>
<tr>
<td>J3130</td>
<td>Injection, testosterone enanthate, up to 200 mg (Use this code for Delatestryl)</td>
</tr>
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There are no specific J codes for the remaining drugs listed in this policy.

REVISIIONS
<table>
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<tr>
<th>Date</th>
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<tbody>
<tr>
<td>01-01-2013</td>
<td>Policy added to the bcbsks.com web site.</td>
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<tr>
<td>06-21-2013</td>
<td>Policy added to the bcbsks.com web site on 05-22-2013. Effective on 06-21-2013, 30 days after posting.</td>
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<td>Revised Title from &quot;Androgens and Anabolic Steroids Prior Authorization and Quantity Limit Criteria&quot; to &quot;Androgens and Anabolic Steroids&quot;</td>
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<td></td>
<td>In Description section:</td>
</tr>
<tr>
<td></td>
<td>▪ Update Description paragraph</td>
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</table>
|           |   ▪ Added Target Drugs chart to reflect the Preferred Topical Androgen Products of: Androderm (testosterone transdermal system) and AndroGel (testosterone gel); and the Non-Preferred Topical Androgen Products of: Axiron (testosterone solution), Bio-T-Gel (testosterone gel), Fortesta (testosterone gel), Striant (testosterone buccal system), Testim (testosterone gel), First-Testosterone (2%
testosterone propionate in white petrolatum compounding kit), and First-Testosterone MC (2% testosterone propionate in moisturizing cream base compounding kit).

- Updated the FDA Approved Indications and Dosage chart.
- Updated the Program Quantity Limits – Topical and Injectable Androgens chart.
- Corrected a duplication error in the FDA Labeled Contraindications chart.

In Policy section:
- Added the following criteria to each drug listing (A 5, B 4, C 4, D 4, E 4, F 3, G 3):
  “ONE of the following:
  a. The patient will be receiving only one androgen or anabolic agent, OR
  b. The prescriber has submitted documentation in support of therapy with more than one agent”

Added Coding section
- Added HCPCS codes: J1070, J1080, J3120, J3130
- Added the statement: "There are no specific J codes for the remaining drugs listed in this policy."

Rationale section updated
References updated

<table>
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<tr>
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<tbody>
<tr>
<td>Description section updated</td>
</tr>
<tr>
<td>- Added Injectable, Oral, and Anabolic Steroid Products chart</td>
</tr>
<tr>
<td>- Added Aveed to FDA Approved Indications, Dosage and Program Quantity Limits, and FDA Labeled Contraindications charts</td>
</tr>
<tr>
<td>- Updated FDA Approved Indications and Dosage, Program Quantity Limits, and FDA Labeled Contraindications charts for existing drugs</td>
</tr>
</tbody>
</table>

In Policy section:
- In Item A 1 a added "or female" to read "Patient is a male or female with AIDS/HIV-associated wasting syndrome..."
- In Item A 2 added "Males only:" to read "Males only: The patient has a measured pretreatment..."
- In Items A 2, B 2, C 2, and D 2 added "or current" and "below the testing laboratory's lower limit of the normal range or is" to read "The patient has a measured pretreatment or current total serum testosterone level that is below the testing laboratory's lower limit of the normal range or is less than 300 ng/dL OR a free serum testosterone level that is below the testing laboratory's lower limit of the normal range"
- In Items A 1 a, B 1 a, and G 1 a corrected "voluntary" to read "involuntary"
- In Item C added "Aveed or" to read "Aveed or Testopel will be approved when..."

Rationale section updated

In Coding section:
- Updated HCPCS Code nomenclature: J1080

References updated

**REFERENCES**


ADDITIONAL INFORMATION

Definition of HIV Wasting Syndrome
The World Health Organization (WHO) clinical diagnosis of HIV wasting syndrome consists of “[u]nexplained involuntary weight loss (>10% baseline body weight), with obvious wasting or body mass index <18.5; PLUS EITHER unexplained chronic diarrhea (loose or watery stools three or more times daily) reported for longer than 1 month OR reports of fever or night sweats for more than one month without other cause and lack of response to antibiotics or antimalarial agents; malaria must be excluded in malarious areas.”

Normal Testosterone Values
The Endocrine Society states “The normative ranges for total and free testosterone levels in healthy young men vary among laboratories and assays. In some laboratories, the lower limit of the normal range for total testosterone level in healthy young men is 280–300 ng/dl (9.8–10.4 nmol/liter). Similarly, in some reference laboratories, the lower limit of the normal range for serum free testosterone level, measured by the equilibrium dialysis method, is 5–9 pg/ml (0.17–0.31 nmol/liter). The clinicians should use the lower limit of normal range for healthy young men established in their laboratory.”

Normal Calcium Values
Normal calcium blood values range from 8.5 to 10.2 mg/dL; may vary slightly among different laboratories.
Additional Information References