TESTOSTERONE AGENTS (ALL DOSAGE FORMS)

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
<th>Length of Authorization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Androderm</td>
<td>Testosterone transdermal patches</td>
<td>Per Medical Guidelines</td>
</tr>
<tr>
<td>Androgel</td>
<td>Testosterone topical gel</td>
<td>Per Medical Guidelines</td>
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<tr>
<td>Aveed</td>
<td>Testosterone injection</td>
<td>Per Medical Guidelines</td>
</tr>
<tr>
<td>Depo-Testosterone</td>
<td>Testosterone injection</td>
<td>Per Medical Guidelines</td>
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<tr>
<td>Striant</td>
<td>Testosterone buccal patches</td>
<td>Per Medical Guidelines</td>
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<tr>
<td>Testopel</td>
<td>Testosterone pellet implant</td>
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</tr>
<tr>
<td>Testosterone</td>
<td>Testosterone injection, topical gel</td>
<td>Per Medical Guidelines</td>
</tr>
</tbody>
</table>

NOTE: Axiron, Fortesta, Testim, Vogelxo, and Natesto are listed as ‘Not Covered’ in the Master PDL

Androgel is Preferred Drug in this Client Product Category

Approvable Criteria for all other forms EXCEPT TESTOSTERONE PELLETS:
(See following page for Testopel Criteria.)

1. Is the member a male?
   • If yes, continue to #2.
   • If no, do not approve.

2. Is the member’s diagnosis hypogonadism (primary or secondary)?
   • If yes, and the request is for a refill, continue to #4.
   • If yes, and the request is for initial/first time treatment, continue to #3.
   • If no, do not approve.

3. For initial treatment only: Do two morning (AM time stamp required) laboratory tests obtained within 90 days of the request confirm Total Serum Testosterone Levels falling below the laboratory normal range? The reference lab range will be used to determine whether the testosterone level is low.
   • If yes, continue to #4.
   • If no, do not approve.

4. Does the member demonstrate signs or symptoms of prostatic hypertrophy?
   • If no, approve for Calendar Year.
   • If yes, proceed to question #5.

5. Is documentation provided of urology referral AND does the member have a recent PSA level within normal limits as defined as ≤ 4 ng/mL (or ≤ 3 ng/mL with high risk factors for prostate cancer)?
   • If no, do not approve.
   • If yes, approve for 6 Months.

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Approvable Criteria for Testosterone Pellets (Testopel):

BFH considers testosterone pellets as 2nd line Testosterone Replacement Therapy (TRT) in males with congenital or acquired endogenous androgen absence or deficiency associated with primary or secondary hypogonadism when oral, intra-muscular, or topical testosterone replacement therapy TRT is ineffective or inappropriate.

- Therefore, in addition to meeting the testosterone criteria listed on the prior page, the member must have tried and failed at least one other TRT formulation for 12 weeks or more prior to receiving approval for Testopel.

TESTOPEL QL = 6 PELLETS EVERY 3 MONTHS
TESTOPEL = SPECIALTY PHARMACY PRODUCT

FDA Approved Indications:
1. Primary hypogonadism (congenital or acquired): Testicular failure because of cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchidectomy, Klinefelter’s syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone levels and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range.
2. Hypogonadotropic hypogonadism (congenital or acquired): Idiopathic gonadotropin or LHRH deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum levels but have gonadotropins in the normal or low range.

NOTE:

Prostatic Hypertrophy: Evidence for an enlarged prostate should prompt referral to an Urologist, and the benefits and risks of treatment should be individualized. PSA scores should be followed every 6 months in these members. Increases in PSA out of the normal range or substantial deterioration in urinary outflow symptoms should prompt discontinuation of therapy. Prostate cancer remains a contraindication to testosterone treatment.

Total Serum – vs – Free Testosterone: Measuring Free Testosterone Levels using the Direct (analog) method is controversial due to its unreliability; therefore this assay should not be considered.

* References:
  - Prescribing Information for all drugs. 2014
  - Winters, Stephen MD. University of Louisville, Division of Endocrinology, Metabolism and Diabetes. Specialty Criteria Review. 2012 August.