Androgens / Anabolic Steroids Prior Authorization with Quantity Limit – Through Preferred Topical Androgen Agent

OBJECTIVE
The intent of the Androgens and Anabolic Steroids Prior Authorization with Quantity Limit (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 agents for the FDA approved indications and off label use that is medically necessary for certain indications (e.g. AIDS/HIV-associated wasting syndrome, Turner Syndrome). In addition, the program will encourage use of a preferred topical androgen product prior to a nonpreferred topical androgen agent. Use of a nonpreferred topical androgen agent 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 agent. Additionally, stand-alone topical agents will not require the use of preferred topical agents, nor be a requirement prior to use of nonpreferred topical agents. The program will approve only one of these agents 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 agents. Quantity limits apply only to the topical and injectable androgens, and will apply to preferred and nonpreferred topical agents.

TARGET AGENTS

Preferred Topical Androgen Agent
AndroGel® 1.62% (testosterone gel)

Non-Preferred Topical Androgen Agents
Androderm® (testosterone transdermal system)
AndroGel 1% (testosterone gel)
Axiron® (testosterone solution)
Fortesta™ (testosterone gel)
Natesto™ (testosterone nasal gel)
Striant® (testosterone buccal system)
Testim® (testosterone gel)
Testosterone (testosterone gel)
Vogelxo™ (testosterone gel)

Stand-alone Topical Androgen Agents
testosterone gel 1% (generic Androgel)
testosterone gel [generic Testim]
testosterone solution [generic Axiron]

Injectable Androgen Products:
Aveed™ (testosterone undecanoate)
testosterone enanthate\textsuperscript{b}
Depo-Testosterone\textsuperscript{®} (testosterone cypionate)\textsuperscript{b}
Testopel\textsuperscript{®} (testosterone pellets)

Oral Androgen Agents:
Android\textsuperscript{®} (methyltestosterone capsule)\textsuperscript{d}
Androxy\textsuperscript{®} (fluoxymesterone tablet)
Methitest\textsuperscript{®} (methyltestosterone tablet)
Testred\textsuperscript{®} (methyltestosterone capsule)\textsuperscript{d}

Anabolic Steroid Agents:
Anadrol-50\textsuperscript{®} (oxymetholone)
danazol\textsuperscript{e}
Oxandrin\textsuperscript{®} (oxandrolone)\textsuperscript{d}

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

**PROGRAM QUANTITY LIMITS – TOPICAL AND INJECTABLE ANDROGENS**

<table>
<thead>
<tr>
<th>Brand (generic)</th>
<th>GPI</th>
<th>Quantity Per Day Limit (or as noted)</th>
<th>Multisource Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Androderm\textsuperscript{®} (testosterone transdermal system)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 mg/day transdermal system</td>
<td>23100030008503</td>
<td>1 patch</td>
<td>M, N, O, or Y</td>
</tr>
<tr>
<td>4 mg/day transdermal system</td>
<td>23100030008510</td>
<td>1 patch</td>
<td>M, N, O, or Y</td>
</tr>
<tr>
<td>AndroGel\textsuperscript{®} / Testosterone (testosterone gel)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1% gel, 25 mg/2.5 gm packet\textsuperscript{b}</td>
<td>23100030004025</td>
<td>2 packets</td>
<td>M, N, O, or Y</td>
</tr>
<tr>
<td>1% gel, 50 mg/5 gm packet\textsuperscript{b}</td>
<td>23100030004030</td>
<td>2 packets</td>
<td>M, N, O, or Y</td>
</tr>
<tr>
<td>1% gel, 75 gm pump (1.25 gm/actuation; 60 actuations/pump)\textsuperscript{b}</td>
<td>23100030004040</td>
<td>10 gm/day (4 pumps/30 days)</td>
<td>M, N, O, or Y</td>
</tr>
<tr>
<td>1.62% gel, 20.25 mg/1.25 gm packet</td>
<td>23100030004044</td>
<td>1 packet</td>
<td>M, N, O, or Y</td>
</tr>
<tr>
<td>1.62% gel, 40.5 mg/2.5 gm packet</td>
<td>23100030004047</td>
<td>2 packets</td>
<td>M, N, O, or Y</td>
</tr>
<tr>
<td>1.62% gel, 75 gm pump (1.25 gm/actuation; 60 actuations/pump)</td>
<td>23100030004050</td>
<td>5 gm/day (2 pumps/30 days)</td>
<td>M, N, O, or Y</td>
</tr>
<tr>
<td>Axiron\textsuperscript{®} (testosterone solution)\textsuperscript{b}</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>30 mg/1.5 mL, 90 mL pump</td>
<td>23100030002020</td>
<td>120 mg/day (2 pumps/30 days)</td>
<td>M, N, O, or Y</td>
</tr>
<tr>
<td>Fortesta\textsuperscript{™}/ Testosterone (testosterone gel)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2% gel, 60 gm pump</td>
<td>23100030004070</td>
<td>80 mg/day\textsuperscript{b,c} (2 pumps/30 days)</td>
<td>M, N, O, or Y</td>
</tr>
<tr>
<td>Natesto\textsuperscript{™} (testosterone nasal gel)</td>
<td></td>
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</tr>
<tr>
<td>5.5 mg/actuation, 7.32 gm pump (60 actuations/pump)</td>
<td>23100030004080</td>
<td>0.732 gm/day (3 pumps/30 days)</td>
<td>M, N, O, or Y</td>
</tr>
<tr>
<td>Striant\textsuperscript{®} (testosterone buccal system)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30 mg buccal system</td>
<td>23100030006320</td>
<td>2 systems</td>
<td>M, N, O, or Y</td>
</tr>
<tr>
<td>Testim\textsuperscript{®}/Testosterone (testosterone gel)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1% gel, 5 gm tube\textsuperscript{b}</td>
<td>23100030004030</td>
<td>2 tubes</td>
<td>M, N, O, or Y</td>
</tr>
<tr>
<td>Vogelxo\textsuperscript{™}/ Testosterone (testosterone gel)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1% gel, 50 mg/5 gm tube</td>
<td>23100030004030</td>
<td>2 tubes (300 gm/30 days)</td>
<td>M, N, O, or Y</td>
</tr>
<tr>
<td>1% gel, 50 mg/5 gm packet</td>
<td>23100030004030</td>
<td>2 packets (300 gm/30 days)</td>
<td>M, N, O, or Y</td>
</tr>
<tr>
<td>Brand (generic)</td>
<td>GPI</td>
<td>Quantity Per Day Limit (or as noted)</td>
<td>Multisource Code</td>
</tr>
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</tr>
<tr>
<td>1% gel, 12.5 mg/actuation, 75 gm pump (carton of 2 pumps)</td>
<td>23100030004040</td>
<td>4 pumps/30 days (300 gm/30 days)</td>
<td>M, N, O, or Y</td>
</tr>
</tbody>
</table>

### Injectable Androgen Agents

#### Aveed™ (testosterone undecanoate)

- 250 mg/mL, 3 mL vial | 23100030802030 | 1 vial/28 days | M, N, O, or Y |
- Testosterone enanthate\(^b\) | 200 mg/mL, 5 mL multiple dose vial | 23100030202010 | 1 vial/28 days | M, N, O, or Y |

#### Depo-Testosterone\(^b\) (testosterone cypionate)

- 100 mg/mL, 10 mL multiple dose vial | 23100030102015 | 1 vial/28 days | M, N, O, or Y |
- 200 mg/mL, 1 mL vial | 23100030102010 | 10 vials/28 days | M, N, O, or Y |
- 200 mg/mL, 10 mL multiple dose vial | 23100030102015 | 1 vial/28 days | M, N, O, or Y |

#### Testopel® (testosterone pellets)

- 75 mg | 23100030008920 | 6 pellets/90 days | M, N, O, or Y |

- 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 – Quantity limit adjusted to accommodate packaging of agent

### TARGET AGENTS – ORAL ANDROGENS AND ANABOLIC STEROIDS

<table>
<thead>
<tr>
<th>Brand (generic)</th>
<th>GPI</th>
<th>Multisource Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral Androgen Agents</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Android(^a) (methyltestosterone)</td>
<td>10 mg capsule(^b)</td>
<td>23100020000105</td>
</tr>
<tr>
<td>Androxy(^a) (fluoxymesterone)</td>
<td>10 mg tablet</td>
<td>2310001000015</td>
</tr>
<tr>
<td>Methitest(^a) (methyltestosterone)</td>
<td>10 mg tablet</td>
<td>2310002000010</td>
</tr>
<tr>
<td>Testred(^a) (methyltestosterone)</td>
<td>10 mg capsule(^b)</td>
<td>23100020000105</td>
</tr>
<tr>
<td>Anabolic Steroid Agents</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anadrol-50(^a) (oxymetholone)</td>
<td>50 mg tablet</td>
<td>23200050000320</td>
</tr>
<tr>
<td>danazol(^a)</td>
<td>50 mg capsule</td>
<td>23100050000105</td>
</tr>
<tr>
<td>100 mg capsule</td>
<td>2310005000110</td>
<td>M, N, O, or Y</td>
</tr>
<tr>
<td>200 mg capsule</td>
<td>2310005000115</td>
<td>M, N, O, or Y</td>
</tr>
<tr>
<td>Oxandrin(^b) (oxandrolone)</td>
<td>2.5 mg tablet</td>
<td>23200040000305</td>
</tr>
<tr>
<td>10 mg tablet</td>
<td>23200040000320</td>
<td>M, N, O, or Y</td>
</tr>
</tbody>
</table>

- a – Brand drug no longer available; available as generic only.
- b – Available as generic and included in the prior authorization program only.

### PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Androderm, AndroGel, Axiron, Fortesta, Natesto, Striant, Testim, Testosterone, or Vogelxo will be approved when ALL of the following are met:

1. The patient has ONE of the following diagnoses:
   a. BOTH of the following:
      i. Patient has 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/m\(^2\) AND all other causes of weight loss have been ruled out

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AND

i. ONE of the following
   1. The patient is female
      OR
   2. The prescriber has provided documentation that checking for testosterone levels is medically inappropriate for the patient’s gender
      OR
   3. ALL of the following:
      a. ONE of the following:
         i. The patient has TWO pretreatment or current serum testosterone levels (free or total) measured in the morning (between 7am and 11am) on two separate days that are below the testing laboratory’s lower limit of the normal range
         OR
         ii. If currently on therapy and a pretreatment level is not available the current total serum testosterone level or free serum testosterone level is below or within the testing laboratory’s normal range
      OR
      b. ALL of the following:
         i. The patient has a diagnosis of primary or secondary (hypogonadotrophic) hypogonadism
         AND
         ii. ALL of the following:
            1. ONE of the following:
               a. The patient has TWO pretreatment or current serum testosterone levels (free or total) measured in the morning (between 7am and 11am) on two separate days that are below the testing laboratory’s lower limit of the normal range
               OR
               b. If currently on therapy and a pretreatment level is not available the current total serum testosterone level or free serum testosterone level is below or within the testing laboratory’s normal range
         AND
         iii. Prior to testosterone replacement therapy, the patient has at least one of the following symptoms of hypogonadism: Sexual dysfunction, loss of body hair, hot flushes or sweats, decreased energy, depression, sleep disturbances, reduced muscle mass and strength, increased body fat
         AND
         iv. Prior to testosterone replacement therapy, the patient has at least one “more specific” symptom of hypogonadism: incomplete or delayed sexual development, decreased libido, decreased spontaneous erections, breast discomfort or gynecomastia, loss of axillary and/or pubic hair, very small (<5 mL) or shrinking testes, infertility due to low sperm count, height loss due to vertebral fractures, low trauma fractures, or low bone density, hot flushes or sweats
         AND
      2. The patient does NOT have any FDA labeled contraindication(s) to the requested agent
      AND
      3. ONE of the following:
         a. The requested agent is a preferred topical androgen product
         OR
b. The requested agent is a stand-alone topical androgen product  
   OR  
c. ONE of the following:  
   i. The patient’s medication history indicates use of a preferred topical androgen  
      OR  
   ii. The patient has a documented intolerance, FDA labeled contraindication,  
      or hypersensitivity to a preferred topical androgen  

AND  

4. ONE of the following:  
b. The patient is not currently being treated with another androgen or anabolic  
   steroid agent (in the past 90 days)  
   OR  
c. The patient will discontinue the current androgen or anabolic steroid agent before  
   starting the requested agent  
   OR  

d. The prescriber has submitted documentation in support of therapy with more than  
   one agent which has been reviewed and approved by the Clinical Review pharmacist  

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 which has  
   been reviewed and approved by the Clinical Review pharmacist  

Length of Approval: 12 months  

Testosterone enanthate, Depo-Testosterone (testosterone cypionate) will be  
approved when ALL of the following are met:  
1. ONE of the following  
   a. The patient has metastatic/inoperable breast cancer  
   OR  
   b. ALL of the following:  
      i. The patient has one of the following diagnoses:  
         1. Patient has 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  
         2. The patient is an adolescent with delayed puberty  
            OR  
         3. BOTH of the following:  
            a. The patient has primary or secondary (hypogonadotrophic)  
               hypogonadism  
               AND  
            b. BOTH of the following:  
               i. Prior to testosterone replacement therapy, the patient  
                  had at least one of the following symptoms of  
                  hypogonadism: Sexual dysfunction, loss of body hair,  
                  hot flushes or sweats, decreased energy, depression,
sleep disturbances, reduced muscle mass and strength, increased body fat

**AND**

ii. Prior to testosterone replacement therapy, the patient had at least one “more specific” symptom of hypogonadism: incomplete or delayed sexual development, decreased libido, decreased spontaneous erections, breast discomfort or gynecomastia, loss of axillary and/or pubic hair, very small (<5 mL) or shrinking testes, infertility due to low sperm count, height loss due to vertebral fractures, low trauma fractures, or low bone density, hot flushes or sweats

**AND**

ii. If the diagnosis is AIDS/HIV wasting or delayed puberty in an adolescent, ONE of the following:

1. ONE of the following:
   a. The patient is male
   OR
   b. The prescriber has provided documentation that checking testosterone levels is medically appropriate for the patient’s age and gender

**AND**

iii. BOTH of the following:

1. ONE of the following:
   a. The patient has TWO pretreatment or current serum testosterone levels (free or total) measured in the morning (between 7am and 11am) on two separate days that are below the testing laboratory’s lower limit of the normal range
   OR
   b. If currently on therapy and a pretreatment level is not available the current total serum testosterone level or free serum testosterone level is below or within the testing laboratory’s normal range

**AND**

6. The patient does NOT have any FDA labeled contraindication(s) to the requested agent

**AND**

7. ONE of the following:
   c. The patient is not currently being treated with another androgen or anabolic steroid agent (in the past 90 days)
   OR
   d. The patient will discontinue the current androgen or anabolic steroid agent before starting the requested agent
   OR
   e. The prescriber has submitted documentation in support of therapy with more than one agent which has been reviewed and approved by the Clinical Review pharmacist

**AND**

8. 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 which has been reviewed and approved by the Clinical Review pharmacist

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

**Aveed** will be approved when ALL of the following are met:
1. The patient has ONE of the following diagnoses:
   a. Patient has primary or secondary (hypogonadotropic) hypogonadism
   **AND**
2. ONE of the following:
   b. The patient has TWO pretreatment or current serum testosterone levels (free or total) measured in the morning (between 7am and 11am) on two separate days that are below the testing laboratory’s lower limit of the normal range **OR**
   c. If currently on therapy and a pretreatment level is not available the current total serum testosterone level or free serum testosterone level is below or within the testing laboratory’s normal range **AND**
3. Males only – BOTH of the following:
   d. Prior to testosterone replacement therapy, the patient has at least one of the following symptoms of hypogonadism: Sexual dysfunction, loss of body hair, hot flushes or sweats, decreased energy, depression, sleep disturbances, reduced muscle mass and strength, increased body fat **AND**
   e. Prior to testosterone replacement therapy, the patient has at least one “more specific” symptom of hypogonadism: incomplete or delayed sexual development, decreased libido, decreased spontaneous erections, breast discomfort or gynecomastia, loss of axillary and/or pubic hair, very small (<5 mL) or shrinking testes, infertility due to low sperm count, height loss due to vertebral fractures, low trauma fractures, or low bone density, hot flushes or sweats **AND**
4. The patient does NOT have any FDA labeled contraindication(s) to the requested agent **AND**
5. ONE of the following:
   f. The patient is not currently being treated with another androgen or anabolic steroid agent (in the past 90 days) **OR**
   g. The patient will discontinue the current androgen or anabolic steroid agent before starting the requested agent **OR**
   h. The prescriber has submitted documentation in support of therapy with more than one agent which has been reviewed and approved by the Clinical Review pharmacist **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 which has been reviewed and approved by the Clinical Review pharmacist
**Length of Approval:** 12 months

*Testopel* will be approved when ALL of the following are met:

1. **ALL of the following:**
   a. **BOTH of the following:**
      i. **ONE of the following:**
         1. **BOTH of the following:**
            a. Patient has primary or secondary (hypogonadotrophic) hypogonadism
            **AND**
            b. **BOTH of the following:**
               i. Prior to replacement therapy, the patient has at least one of the following symptoms of hypogonadism: Sexual dysfunction, loss of body hair, hot flushes or sweats, decreased energy, depression, sleep disturbances, reduced muscle mass and strength, increased body fat
               **AND**
               ii. Prior to testosterone replacement therapy, the patient has at least one “more specific” symptom of hypogonadism: incomplete or delayed sexual development, decreased libido, decreased spontaneous erections, breast discomfort or gynecomastia, loss of axillary and/or pubic hair, very small (<5 mL) or shrinking testes, infertility due to low sperm count, height loss due to vertebral fractures, low trauma fractures, or low bone density, hot flushes or sweats
      OR
   2. **BOTH of the following:**
      a. **ONE of the following:**
         i. The patient is male
         **OR**
         ii. The prescriber has provided documentation that the requested agent is medically appropriate for the patient’s gender
      **AND**
      b. The patient is an adolescent with delayed puberty
      **AND**
      ii. **ONE of the following:**
          1. The patient has TWO pretreatment or current serum testosterone levels (free or total) measured in the morning (between 7am and 11am) on two separate days that are below the testing laboratory’s lower limit of the normal range
          **OR**
          2. If currently on therapy and a pretreatment level is not available the current total serum testosterone level or free serum testosterone level is below or within the testing laboratory’s normal range
      **AND**
   2. The patient does NOT have any FDA labeled contraindication(s) to the requested agent
   **AND**
   3. **ONE of the following:**
      i. The patient is not currently being treated with another androgen or anabolic steroid agent (in the past 90 days)
j. The patient will discontinue the current androgen or anabolic steroid agent before starting the requested agent

k. The prescriber has submitted documentation in support of therapy with more than one agent which has been reviewed and approved by the Clinical Review pharmacist

AND

4. 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 which has been reviewed and approved by the Clinical Review pharmacist

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

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

1. ONE of the following:
   a. ALL of the following:
      i. ONE of the following:
         1. The patient has cryptorchidism
         OR
         2. BOTH of the following:
            a. The patient has hypogonadism
            AND
            b. BOTH of the following:
               i. Prior to testosterone replacement therapy, the patient has at least one of the following symptoms of hypogonadism: Sexual dysfunction, loss of body hair, hot flushes or sweats, decreased energy, depression, sleep disturbances, reduced muscle mass and strength, increased body fat
               AND
               ii. Prior to testosterone replacement therapy, the patient has at least one “more specific” symptom of hypogonadism: incomplete or delayed sexual development, decreased libido, decreased spontaneous erections, breast discomfort or gynecomastia, loss of axillary and/or pubic hair, very small (<5 mL) or shrinking testes, infertility due to low sperm count, height loss due to vertebral fractures, low trauma fractures, or low bone density, hot flushes or sweats

      OR

   3. BOTH of the following:
      a. ONE of the following:
         i. The patient is male
         OR
ii. The prescriber has provided documentation that checking testosterone levels is medically appropriate for the patient’s age and gender

**AND**

b. The patient is an adolescent with delayed puberty

**AND**

ii. **BOTH** of the following:
   1. **ONE** of the following:
      a. The patient has **TWO** pretreatment or current serum testosterone levels (free or total) measured in the morning (between 7am and 11am) on two separate days that are below the testing laboratory’s lower limit of the normal range
      OR
      b. If currently on therapy and a pretreatment level is not available the current total serum testosterone level or free serum testosterone level is below or within the testing laboratory’s normal range

**OR**

b. Patient has metastatic/inoperable breast cancer

**AND**

2. The patient does **NOT** have any FDA labeled contraindication(s) to the requested agent

**AND**

3. **ONE** of the following:
   a. The patient is not currently being treated with another androgen or anabolic steroid agent (in the past 90 days)
   OR
   b. The patient will discontinue the current androgen or anabolic steroid agent before starting the requested agent
   OR
   c. The prescriber has submitted documentation in support of therapy with more than one agent which has been reviewed and approved by the Clinical Review pharmacist

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

**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:
      i. The patient’s medication history indicates previous use of an erythropoiesis-stimulating agent **OR**
      ii. 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) to the requested agent

**AND**

4. **ONE** of the following:
a. The patient is not currently being treated with another androgen or anabolic steroid agent (in the past 90 days)

OR

b. The patient will discontinue the current androgen or anabolic steroid agent before starting the requested agent

OR

c. The prescriber has submitted documentation in support of therapy with more than one agent which has been reviewed and approved by the Clinical Review pharmacist

**Length of Approval:** 12 months

**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) to the requested agent **AND**
3. ONE of the following:
   a. The patient is not currently being treated with another androgen or anabolic steroid agent (in the past 90 days)

OR

b. The patient will discontinue the current androgen or anabolic steroid agent before starting the requested agent

OR

c. The prescriber has submitted documentation in support of therapy with more than one agent which has been reviewed and approved by the Clinical Review pharmacist

**Length of Approval:** 12 months

**Oxandrin (oxandrolone)** will be approved when ALL of the following are met:
1. The patient has ONE of the following diagnoses:
   a. Patient has 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 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**
   e. Patient is on long-term administration of oral or injectable corticosteroids **AND**
2. The patient does NOT have any FDA labeled contraindication(s) to the requested agent **AND**
3. ONE of the following:
   a. The patient is not currently being treated with another androgen or anabolic steroid agent (in the past 90 days)

OR

b. The patient will discontinue the current androgen or anabolic steroid agent before starting the requested agent
OR
c. The prescriber has submitted documentation in support of therapy with more than one agent which has been reviewed and approved by the Clinical Review pharmacist

**Length of Approval:** 12 months