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)[d]

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

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

Injectable Androgen Products:
Aveed™ (testosterone undecanoate)

testosterone enanthate[b]
Depo-Testosterone® (testosterone cypionate)[b]
Testopel® (testosterone pellets)

Oral Androgen Agents:
Android® (methyltestosterone capsule)[d]
Androxy® (fluoxymesterone tablet)
Methitest® (methyltestosterone tablet)
Testred® (methyltestosterone capsule)[d]

Anabolic Steroid Agents:
Anadrol-50® (oxymetholone)
danazol[c]
Oxandrin® (oxandrolone)[d]

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

PROGRAM QUANTITY LIMITS – TOPICAL AND INJECTABLE ANDROGENS

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

Brand (generic)	GPI	Quantity Per Day Limit (or as noted)	Multisource Code
1% gel, 12.5 mg/actuation, 75 gm pump (carton of 2 pumps)	23100030004040	4 pumps/30 days (300 gm/30 days)	M, N, O, or Y
Injectable Androgen Agents			
Aveed™ (testosterone undeconoate)			
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® (testosterone cypionate)[b]			
100 mg/mL, 10 mL multiple dose vial	23100030102010	1 vial/28 days	M, N, O, or Y
200 mg/mL, 1 mL vial	23100030102015	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

Brand (generic)	GPI	Multisource Code
Oral Androgen Agents		
Android® (methyltestosterone)		
10 mg capsule[b]	23100020000105	M, N, O, or Y
Androxy® (fluoxymesterone)		
10 mg tablet	23100010000315	M, N, O, or Y
Methitest® (methyltestosterone)		
10 mg tablet	23100020000310	M, N, O, or Y
Testred® (methyltestosterone)		
10 mg capsule[b]	23100020000105	M, N, O, or Y
Anabolic Steroid Agents		
Anadrol-50® (oxymetholone)		
50 mg tablet	23200050000320	M, N, O, or Y
danazol[a]		
50 mg capsule	23100005000105	M, N, O, or Y
100 mg capsule	23100005000110	M, N, O, or Y
200 mg capsule	23100005000115	M, N, O, or Y
Oxandrin® (oxandrolone)[b]		
2.5 mg tablet	23200040000305	M, N, O, or Y
10 mg tablet	23200040000320	M, N, O, or Y

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

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 (hypogonadotropic) 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 lowsperm 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/m^2 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 (hypogonadotropic) 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
   9. 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
      10. 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
         11. The patient does NOT have any FDA labeled contraindication(s) to the requested agent
         AND
         12. 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
            13. 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 (hypogonadotropic) 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)

OR

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

OR

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/m^2) 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