BlueCross BlueShield of Alabama

Androgens and Anabolic Steroids Prior Authorization with Quantity Limit Through Preferred Topical Androgen Program Summary

This prior authorization program will apply only to the Oral and Topical Androgens and Anabolic Steroids.
Preferred topical agents is Androgel 1.62%.
This program applies to Commercial, GenPlus, NetResults A series, SourceRx and Health Insurance Marketplace formularies.
Quantity limits only apply to the topical androgen agents.

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 the preferred topical androgen agents (Androgel 1.62%) prior to a non-preferred topical androgen agent. Use of a non-preferred 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 the preferred topical androgen agents. Additionally, stand-alone topical agents will not require the use of preferred topical agents, nor be a requirement prior to use of non-preferred topical agents. The program will approve only one of these agents at a time. The program will approve topical 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 androgens.

TARGET AGENTS

Topical Androgen Agents:

Preferred Agent

AndroGel® 1.62% (testosterone gel 1.62%)[c]

Non-preferred Agents

Androderm® (testosterone transdermal system)
AndroGel® 1% (testosterone gel 1%)[a]
Axiron® (testosterone solution)[a]
Fortesta™ (testosterone gel)
Natesto™ (testosterone nasal gel)
Striant® (testosterone buccal system)
Testim® (testosterone gel)[a]
Testosterone (testosterone gel)
Vogelxo™ (testosterone gel)

Stand-alone Agents

testosterone gel [generic AndroGel 1%, generic Testim]
testosterone solution [generic Axiron]

Oral Androgen Agents:

Android® (methyltestosterone capsule)[b]
Androxy® (fluoxymesterone tablet)
Methitest® (methyltestosterone tablet)
Testred® (methyltestosterone capsule)[b]

Anabolic Steroid Agents:

Anadrol-50® (oxymetholone)
danazol[c]
Oxandrin® (oxandrolone)[b]

a – Generic available and included in prior authorization and quantity limit programs as a stand-alone product.
b – Generic available and included in prior authorization program only.
c- Generic anticipated and will be included in prior authorization and quantity limit.

PROGRAM QUANTITY LIMITS – TOPICAL 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)	23100030004040	10 gm/day (4 pumps/30 days)	M, N, O, or Y
1% gel, 2 x 75 gm pump (1.25 gm/actuation; 60 actuations/pump)	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
Bio-T-Gel™ (testosterone gel)			
1% gel, 25 mg/2.5 gm packet	GPI not available	2 packets	M, N, O, or Y
1% gel, 50 mg/5 gm packet	GPI not available	2 packets	M, N, O, or Y
Fortesta™ / Testosterone (testosterone gel)			
2% gel, 60 gm pump	23100030004070	80 mg/day[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 gram/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)[b]			
1% gel, 5 gm tube	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
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

TARGET AGENTS – ORAL ANDROGENS AND ANABOLIC STEROIDS

Brand (generic)	GPI	Multisource Code
Oral Androgen Agents		
Android® (methyltestosterone)[b]		
10 mg capsule	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)[b]		
10 mg capsule	23100020000105	M, N, O, or Y
Anabolic Steroid Agents		
Anadrol-50® (oxymetholone)		
50 mg tablet	23200050000320	M, N, O, or Y
danazol [Danocrine®][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, Bio-T-Gel, Fortesta, Natesto, Striant, Testim, Testosterone, or Vogelxo will be approved when ALL of the following are met:

1. ONE of the following:
    a. BOTH of the following:
        i. The 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
        ii. 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. The patient has ONE of the following levels (documentation requirement to be determined by client):
                a. The patient is not currently receiving testosterone replacement therapy AND has ONE of the following pretreatment levels:
                    i. 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
                    ii. Free serum testosterone level that is below the testing laboratory's lower limit of the normal range
                OR
                b. The patient is currently receiving testosterone replacement therapy AND the patient has ONE of the following current levels:

i. Total serum testosterone level that is within OR below the testing laboratory's lower limit of the normal range OR is less than 300 ng/dL
OR
ii. Free serum testosterone level is within OR below the testing laboratory's normal range

OR

b. ALL of the following:
   i. The patient has primary or secondary (hypogonadotropic) hypogonadism
   AND
   ii. Prior to testosterone replacement therapy, the patient had sign/symptom of hypogonadism
   AND
   iii. ONE of the following levels (documentation requirement to be determined by client):
      1. The patient is not currently receiving testosterone replacement therapy AND has ONE of the following pretreatment levels:
         a. 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
         b. Free serum testosterone level that is below the testing laboratory's lower limit of the normal range

      OR

      2. The patient is currently receiving testosterone replacement therapy AND the patient has ONE of the following current levels:
         a. Total serum testosterone level that is within OR below the testing laboratory's lower limit of the normal range OR is less than 300 ng/dL
         OR
         b. Free serum testosterone level is within OR below the testing laboratory's normal range

OR

c. The patient has a diagnosis of gender identity disorder (GID) and ALL of the following:
   i. The patient is an adult (18 years of age or older)
   AND
   ii. The patient has received evaluation from TWO qualified mental health professionals who have independently assessed the patient and ALL of the following:
      1. At least one of the evaluating professionals must have a doctoral degree (PhD, MD, Ed.B, D.Sc, D.S.W. or Psy.D) and be capable of adequately evaluating co-morbid psychiatric conditions
      AND
      2. One evaluation should be from a person who has only had an evaluative role with the patient
      AND
      3. The evaluations document that the patient has demonstrated a knowledge and understanding of the expected outcomes of cross-sex hormone treatment, as well as the medical and social risks and benefits

   AND

   iii. ONE of the following:
      1. The patient does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment
      OR

2. If the patient has significant medical or mental health issues present, they must be reasonably well controlled and noted in the medical documentation submitted

AND

iv. For patients new to therapy, the patient has completed at least 12 continuous months of living in a congruent gender role with his/her gender identity (real life experience) prior to cross-sex hormone treatment (this should be noted in medical documentation submitted including start/end dates)

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 agent (Androgel 1.62%)
      OR
   b. The requested agent is a stand-alone topical androgen agent
      OR
   c. ONE of the following:
      i. The patient's medication history indicates use of a preferred topical androgen agent (Androgel 1.62%)
         OR
      ii. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a preferred topical androgen 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

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

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. Prior to testosterone replacement therapy, the patient had sign/symptom of hypogonadism

OR

3. 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 is not currently receiving testosterone replacement therapy AND has ONE of the following pretreatment levels:
        a. 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

        b. Free serum testosterone level that is below the testing laboratory's lower limit of the normal range

    OR

    2. The patient is currently receiving testosterone replacement therapy AND the patient has ONE of the following current levels:
        a. Total serum testosterone level that is within OR below the testing laboratory's lower limit of the normal range OR is less than 300 ng/dL

        OR

        b. Free serum testosterone level is within OR below the testing laboratory's normal range

OR

b. The patient has metastatic/inoperable breast cancer

OR

c. The patient has a diagnosis of gender identity disorder (GID) and ALL of the following:
    i. The patient is an adult (18 years of age or older)

    AND

    ii. The patient has received evaluation from TWO qualified mental health professionals who have independently assessed the patient and ALL of the following:
        1. At least one of the evaluating professionals must have a doctoral degree (PhD, MD, Ed.B, D.Sc, D.S.W. or Psy.D) and be capable of adequately evaluating co-morbid psychiatric conditions

        AND

        2. One evaluation should be from a person who has only had an evaluative role with the patient

        AND

        3. The evaluations document that the patient has demonstrated a knowledge and understanding of the expected outcomes of cross-sex hormone treatment, as well as the medical and social risks and benefits

    AND

    iii. ONE of the following:

1. The patient does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment
   OR
2. If the patient has significant medical or mental health issues present, they must be reasonably well controlled and noted in the medical documentation submitted

AND

iv. For patients new to therapy, the patient has completed at least 12 continuous months of living in a congruent gender role with his/her gender identity (real life experience) prior to cross-sex hormone treatment (this should be noted in medical documentation submitted including start/end dates)

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. ONE of the following:
   a. BOTH of the following:
      i. The patient has ONE of the following diagnoses:
         1. 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
         2. Patient has anemia associated with chronic renal failure AND ONE of the following:
            a. The patient's medication history indicates previous use of an erythropoiesis-stimulating agent
               OR
            b. The patient has documented intolerance, FDA labeled contraindication or hypersensitivity to an erythropoiesis-stimulating agent

      AND

      ii. The patient has a hematocrit (Hct) value <30%

      OR

   b. The patient has a diagnosis of gender identity disorder (GID) and ALL of the following:
      i. The patient is an adult (18 years of age or older)
         AND

ii. The patient has received evaluation from TWO qualified mental health professionals who have independently assessed the patient and ALL of the following:
    1. At least one of the evaluating professionals must have a doctoral degree (PhD, MD, Ed.B, D.Sc, D.S.W. or Psy.D) and be capable of adequately evaluating co-morbid psychiatric conditions
    AND
    2. One evaluation should be from a person who has only had an evaluative role with the patient
    AND
    3. The evaluations document that the patient has demonstrated a knowledge and understanding of the expected outcomes of cross-sex hormone treatment, as well as the medical and social risks and benefits

AND

iii. ONE of the following:
    1. The patient does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment
    OR
    2. If the patient has significant medical or mental health issues present, they must be reasonably well controlled and noted in the medical documentation submitted

AND

iv. For patients new to therapy, the patient has completed at least 12 continuous months of living in a congruent gender role with his/her gender identity (real life experience) prior to cross-sex hormone treatment (this should be noted in medical documentation submitted including start/end dates)

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

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
    OR
    d. The patient has a diagnosis of gender identity disorder (GID) and ALL of the following:

i. The patient is an adult (18 years of age or older)
AND
ii. The patient has received evaluation from TWO qualified mental health professionals who have independently assessed the patient and ALL of the following:
1. At least one of the evaluating professionals must have a doctoral degree (PhD, MD, Ed.B, D.Sc, D.S.W. or Psy.D) and be capable of adequately evaluating co-morbid psychiatric conditions
AND
2. One evaluation should be from a person who has only had an evaluative role with the patient
AND
3. The evaluations document that the patient has demonstrated a knowledge and understanding of the expected outcomes of cross-sex hormone treatment, as well as the medical and social risks and benefits
AND
iii. ONE of the following:
1. The patient does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment
OR
2. If the patient has significant medical or mental health issues present, they must be reasonably well controlled and noted in the medical documentation submitted
AND
iv. For patients new to therapy, the patient has completed at least 12 continuous months of living in a congruent gender role with his/her gender identity (real life experience) prior to cross-sex hormone treatment (this should be noted in medical documentation submitted including start/end dates)

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. BOTH of the following:

i. ONE of the following:
   1. The patient is female
      OR
   2. The prescriber has provided documentation that the requested agent is medically appropriate for the patient's gender

AND

ii. 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

OR

f. The patient has a diagnosis of gender identity disorder (GID) and ALL of the following:
   i. The patient is an adult (18 years of age or older)

   AND

   ii. The patient has received evaluation from TWO qualified mental health professionals who have independently assessed the patient and ALL of the following:
      1. At least one of the evaluating professionals must have a doctoral degree (PhD, MD, Ed.B, D.Sc, D.S.W. or Psy.D) and be capable of adequately evaluating co-morbid psychiatric conditions

      AND

      2. One evaluation should be from a person who has only had an evaluative role with the patient

      AND

      3. The evaluations document that the patient has demonstrated a knowledge and understanding of the expected outcomes of cross-sex hormone treatment, as well as the medical and social risks and benefits

   AND

   iii. ONE of the following:
      1. The patient does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment

      OR

      2. If the patient has significant medical or mental health issues present, they must be reasonably well controlled and noted in the medical documentation submitted

   AND

   iv. For patients new to therapy, the patient has completed at least 12 continuous months of living in a congruent gender role with his/her gender identity (real life experience) prior to cross-sex hormone treatment (this should be noted in medical documentation submitted including start/end dates)

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

FDA APPROVED INDICATIONS AND DOSAGE[1-11,26,27,30,31,35-37,39,43,47]

Topical Androgen Agents		
Agent	**Indication**	**Dosage and Administration**
Androderm® (testosterone transdermal system) 2 mg/day, 4 mg/day transdermal system	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, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. -Hypogonadotropic hypogonadism (congenital or acquired): idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation.	Hypogonadism <u>2 mg/day and 4 mg/day system</u> -Recommended starting dose is one 4 mg/day system (not two 2 mg/day systems) applied nightly for 24 hours. -Dose may be decreased to 2 mg (i.e., one 2 mg/day system) or increased to 6 mg (i.e., one 4 mg/day and one 2 mg/day system) <u>Switching from 2.5 mg/day, 5 mg/day, and 7.5 mg/day to 2 mg/day, 4 mg/day and 6 mg/day dosage</u> -Patients using 2.5 mg daily may be switched to 2 mg/day systems at the next scheduled dose -Patients using 5 mg daily may be switched to 4 mg/day systems at the next scheduled dose -Patients using 7.5 mg daily may be switched to 6 mg (2 mg/day and 4 mg/day systems) at the next scheduled dose
AndroGel® / Testosterone (testosterone gel) 1% gel: 25 mg/2.5 gm packet[b] 50 mg/5 gm packet[b] 75 gm pump (12.5 mg testosterone/actuation; 60 actuations/pump[b]) 1.62% gel: 75 gm pump (20.25 mg testosterone/actuation; 60 actuations/pump) 20.25 mg/1.25gm packet 40.5 mg/2.5 gm packet		<u>1% gel</u>: -Initial dose is 50 mg of testosterone (4 pump actuations, two 25 mg packets, or one 50 mg packet) 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. <u>1.62% gel</u>: -40.5 mg of testosterone (2 pump actuations or 1 40.5 mg packet) applied topically once daily in the morning. -Dose may be adjusted between a minimum of 20.25 mg testosterone (1 pump actuation or 1 packet) or maximum 81 mg testosterone (4 pump actuations or 2 40.5 mg packets) based on measured serum testosterone levels.

Topical Androgen Agents		
Agent	**Indication**	**Dosage and Administration**
Axiron® (testosterone soln)[b] 30 mg/1.5 mL, 90 mL pump		-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 (testosterone gel) 2% gel		-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.
Natesto™ (testosterone nasal gel)		Recommended dose of 11 mg (2 pump actuations, one per nostril), applied intranasally 3 times daily. If total testosterone concentrations consistently exceed 1040 ng/dL, therapy should be discontinued. If total testosterone concentrations are consistently below 300 ng/dL, an alternative treatment should be considered. Not recommended for use with nasally administered drugs other than sympathomimetic decongestants (e.g., oxymetazoline)
Striant® (testosterone buccal system) 30 mg buccal system		Usual dose is one buccal system (30 mg) to the gum region twice daily, morning and evening (about 12 hours apart).
Testim® /Testosterone (testosterone gel)[b] 1% gel		-Initial dose is 50 mg of testosterone (one tube) once daily in the morning. -Dose may be increased to 100 mg testosterone (two tubes) once daily based on measured serum testosterone.

Topical Androgen Agents		
Agent	**Indication**	**Dosage and Administration**
Vogelxo™/Testosterone (testosterone gel) 1% gel	For testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: -Primary hypogonadism -Hypogonadotropic hypogonadism (congenital or acquired)	1% gel: -Initial dose is 50 mg testosterone (5 gm gel) once daily at the same time each day. -Dose may be increased to 100 mg daily based on measured serum testosterone levels. -The maximum recommended dose is 100 mg once daily.

a – Brand drug no longer available; available as generic only.
b – Generic available.

Oral Androgen and Anabolic Agents		
Agent	**Indication**	**Dosage and Administration**
Android® (methyltestosterone) 10 mg capsule[b] **Methitest®** (methyltestosterone) 10 mg tablet **Testred®** (methyltestosterone) 10 mg capsule[b]	Males: Androgen replacement therapy related to the following: -Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsions, orchitis, vanishing testis syndrome; or orchidectomy -Hypogonadotropic hypogonadism (congenital or acquired) - idiopathic gonadotropin or LHRH deficiency, or pituitary hypothalamic injury from tumors, trauma, or radiation -Delayed puberty in males Females: Palliative treatment of breast cancer in women	Males: -Androgen replacement therapy related to hypogonadism: 10 mg to 50 mg/day -Androgen replacement therapy related to cryptorchidism: 10 mg 3 times daily -Delayed puberty (adolescents only): 5 mg to 25 mg/day for a limited period, usually for 4 to 6 months Females: -50 mg once daily up to four times/day -If suitable response within 2-4 weeks, decrease to 25 mg two times daily
Androxy® (fluoxymesterone) 10 mg tablet	Males: -Androgen replacement therapy in male hypogonadism -Treatment of delayed puberty in males Females: Inoperable breast cancer	Males: -Androgen replacement: 5 mg given 1 to 4 times daily, although higher initial doses (i.e. 10 mg/day) with subsequent dose adjustment are usually preferable -Delayed puberty (adults/adolescents): 2.5 mg - 10 mg daily for up to 4 to 6 months. Doses up to 20 mg daily have been used. Females: 10 mg - 40 mg per day in divided doses. Treatment should continue at least 2-3 months

Oral Androgen and Anabolic Agents		
Agent	**Indication**	**Dosage and Administration**
Anadrol-50® (oxymetholone) 50 mg tablet	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	Adults and children -1 to 5 mg/kg body weight per day. -Usual effective dose is 1 to 2 mg/kg/day; higher doses may be required, dose should be individualized. -Response is not often immediate; minimum trial of 3 to 6 months should be given -Following remission, some patients may be maintained without the drugs; others may be maintained on an established lower daily dosage -A continued maintenance dose is usually necessary in patients with congenital aplastic anemia
danazol[a] 50 mg, 100 mg, 200 mg capsule	-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. NOTE: If danazol therapy initiated during exacerbation of angioedema caused by trauma, stress or other causes, periodic attempts to reduce or discontinue therapy should be considered -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.

Oral Androgen and Anabolic Agents		
Agent	**Indication**	**Dosage and Administration**
Oxandrin® (oxandrolone)[b] 2.5 mg, 10 mg tablet	-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

a – Brand drug no longer available; available as generic only.
b – Generic available.

Injectable Androgen Agents		
Agent	**Indication**	**Dosage and Administration**

testosterone enanthate[b]
 	
200 mg/mL
	Males:
	For replacement therapy in 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, 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:
		-Hypogonadism
		• Adult males: 50 mg to 400 mg IM every 2 to 4 weeks
		• Children (initiation of pubertal growth): 40 mg to 50 mg/m^2 IM monthly until growth rate falls to prepubertal levels.
		  ○ Terminal growth phase: 100 mg/m^2 IM monthly until growth ceases
		  ○ Maintenance of virilization: 100 mg/m^2 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/m^2/dose IM monthly for 6 months
		
		Females:
		-Palliation of inoperable breast cancer: 200 mg to 400 mg IM every 2 to 4 weeks

Injectable Androgen Agents		
Agent	**Indication**	**Dosage and Administration**
Depo-Testosterone® (testosterone cypionate)[b] 100 mg/mL, 200 mg/mL	For replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone: -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 LHRH deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation.	-Hypogonadism: 50-400 mg every 4 weeks
Testopel® (testosterone pellets) 75 mg	Males -Primary hypogonadism (congenital or acquired): testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome; or orchiectomy -Hypogonadotropic hypogonadism (congenital or acquired): idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. -Delayed puberty	-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

Injectable Androgen Agents		
Agent	**Indication**	**Dosage and Administration**
Aveed™ (testosterone undecanoate) 250 mg/mL	-Primary hypogonadism (congenital or acquired): testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome; or orchiectomy -Hypogonadotropic hypogonadism (congenital or acquired): idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation	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.

CLINICAL RATIONALE
Efficacy
Androgen Deficiency Syndromes
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]

Testosterone replacement therapy should be initiated in symptomatic men with hypogonadism with a subnormal serum testosterone.[12,51] Signs and symptoms of hypogonadism include:[12]

- More specific:
  - Incomplete or delayed sexual development, eunuchoidism
  - Reduced sexual desire (libido) and activity
  - Decreased spontaneous erections
  - Breast discomfort, gynecomastia
  - Loss of body (axillary and pubic) hair, reduced shaving
  - Very small (especially <5 ml) or shrinking testes
  - Inability to father children, low or zero sperm count
  - Height loss, low trauma fracture, low bone mineral density
  - Hot flushes, sweats
- Less specific:
  - Decreased energy, motivation, initiative, and self-confidence
  - Feeling sad or blue, depressed mood, dysthymia
  - Poor concentration and memory
  - Sleep disturbance, increased sleepiness
  - Mild anemia (normochromic, normocytic, in the female range)
  - Reduced muscle bulk and strength
  - Increased body fat, body mass index
  - Diminished physical or work performance

The principal goal of testosterone therapy is to restore serum testosterone concentration to normal range.[51]

In an FDA safety communication [03-03-2015], FDA cautioned that the benefit and safety of these medications have not been established for the treatment of low testosterone levels due

to aging, even if a man's symptoms seem related to low testosterone. Testosterone product manufacturers must clarify approved uses, and add information to labeling regarding possible increased risk of heart attacks and strokes in patients taking testosterone. Testosterone is FDA-approved as replacement therapy only for men who have low testosterone levels due to disorders of the testicles, pituitary gland, or brain that cause a condition called hypogonadism. Examples of these disorders include failure of the testicles to produce testosterone due to genetic problems, or damage from chemotherapy or infection. FDA has become aware that testosterone is being used extensively in attempts to relieve symptoms in men who have low testosterone for no apparent reason other than aging. The benefits and safety of this use have not been established.[42]

Hereditary Angioedema (HAE)
A review (2015) states despite lack of large, randomized, placebo-controlled trials, the efficacy of attenuated androgens (e.g., danazol) in the long-term prophylaxis of type I and II HAE is well established and widely accepted. Advantages of androgen use include convenience of oral dosing and low medication cost relative to other HAE therapies. The minimum effective androgen dose that controls HAE attacks is recommended to reduce risk of short-term and long-term adverse effects. Androgen therapy may be effective for most patients with HAE; however, potential risks and adverse effects must be carefully considered and discussed with patients when considering options for long term HAE prophylaxis. In keeping with current HAE consensus guidelines, disease management programs should be tailored individually, taking into consideration patient priorities and preferences, preexisting comorbid medical conditions, and the risk benefit profiles of different treatment options.[46]

A review on treatment of HAE (2014) suggests attenuated androgens and plasma-derived C1-inhibitor (C1-INH) concentrates are the recommended options for long term prophylaxis of HAE. Antifibrinolytic agents have also undergone controlled clinical trials against placebo, but the efficacy data for them is inferior. Danazol is the most commonly used androgen.
An alternative for short-term prophylaxis is initiation of daily danazol 5 to 7 days before a procedure and 2 days after the procedure. Efficacy of androgens vs. C1-INH replacement has not been studied for preprocedural prophylaxis. Androgens may be used when the surgery-related risk is relatively low and when C1-INH concentrate is not available. Adverse events with short-term use of androgens are minimal. They are less expensive and easier to use although they are not suitable for pregnant and nursing females. Long-term treatment with androgens is associated with a wide range of potential, dose-dependent adverse effects. Risks may outweigh benefits if dose is more than equivalent of 200 mg of danazol daily.[41]

The U.S. HAE Association Medical Advisory Board (2013) recommendations for patients with HAE due to C1-INH deficiency list danazol among treatment options for prophylaxis of HAE. The only other FDA approved agent is plasma derived C1-INH therapy; other options are used off label. It is the position of the board that these medications should not be used in patients who express a preference for an alternative therapy and that patients should not be required to fail androgen therapy as a prerequisite to receiving prophylactic C1-INH concentrate.[40]

It is important to avoid anabolic androgens for long-term prophylaxis in patients age <16 or in pregnant or breastfeeding women. Anabolic androgens should also be avoided if not tolerated or there are troubling adverse effects. All patients receiving attenuated androgens need to be carefully followed-up for the potential of medication-related adverse effects.[40]

Evidence based recommendations for the Therapeutic Management of Angioedema due to hereditary C1 inhibitor deficiency: Consensus Report of an International Working Group (2012) states the following: There was consensus that danazol can be considered for long term prophylaxis for patients who are >16 years of age and non-pregnant and non-lactating women (in those patients who can tolerate it and the dosage does not exceed 200 mg/day).[32]

The World Allergy Organization guideline (2012) for the management of HAE also states danazol may be used for short term/pre-procedural prophylaxis when the surgery-related risk is relatively low and when C1-INH concentrate is not available. Advantages are ease of use, good tolerability for most, including children, and low cost. Disadvantages are perceived inferior efficacy to C1-INH concentrate (although evidence is lacking), use in case of elective surgery only, side effects and unsuitability for pregnant (except last trimester) or breastfeeding women.[33]

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[16], testosterone enanthate[17,18,21], oxandrolone[19,20], and cypionate[45]. The use of topical testosterone to treat AIDS wasting in women is supported by several studies.[28,29] Oxandrolone was studied in both male and female pediatric patients.[20] 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).[15] 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.[22] 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.[23]

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.[24] 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.[27] 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.[25]

The American Urology Association (AUA) recommends that phosphodiesterase type 5 inhibitors should be first-line therapy for erectile dysfunction. AUA also recommend that testosterone therapy is not indicated for the treatment of erectile dysfunction in patients with a normal serum testosterone level. Also, the role of testosterone therapy in men with sexual dysfunction with low, borderline normal, and normal testosterone levels is not well defined.[38]

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.[13] 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.[14] Anabolic steroids are mainly abused by males and athletes to increase muscle mass and improve athletic performance.

On September 17, 2014, the FDA Bone, Reproductive and Urologic Drugs Advisory Committee stated that the available studies informing the cardiovascular safety signal with testosterone therapy are limited in scope, quality, design, and size. Nonetheless, there was agreement amongst committee members that a weak signal of cardiovascular risk had emerged from results of cardiovascular-related adverse events with testosterone use. The committee agreed that additional studies on the risk of therapy are needed to assess cardiovascular and other risks associated with short term and long term use of testosterone for age-related hypogonadism.[34]

Prescribing information (2015) for testosterone products contains the following warnings: Venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients using testosterone products. Some postmarketing studies have shown an increased risk of myocardial infarction and stroke associated with the use of testosterone replacement therapy. Safety and efficacy in men with "age-related hypogonadism" have not been established. Safety and efficacy in males less than 18 years old have not been established.

A retrospective cohort study (2015) compared cardiovascular safety of testosterone injections, patches, and gels. Adult male initiators (N=431,687) of new dosage formulations of testosterone patches, gels, or injections following 180 days free of any testosterone use were followed for up to one year of use. Of the subjects followed, 36% used injection products, 9% used patch products, and 55% used gel products. Testosterone injections were associated with a greater risk of CV events, hospitalizations, and deaths vs. gels. Patches and gels had similar risk profiles. This study did not assess whether patients met criteria for use of testosterone and did not assess the safety of testosterone among users compared to non-users of the drug.[44]

On October 25th, 2016, the FDA approved a class wide labeling changes for all prescription testosterone products, adding a new Warning and updating the Abuse and Dependence section to include new safety information from published literature and case reports regarding the risks associated with abuse and dependence of testosterone and other Androgen, Anabolic Steroids (AAS). The new Warning will alert prescribers to the abuse potential of testosterone and the serious adverse outcomes, especially those related to heart and mental health that have been reported in association with testosterone/AAS abuse. In addition to the new Warning, all testosterone labeling has been revised to include information in the Abuse and Dependence section about adverse outcomes reported in association with abuse and dependence of testosterone/AAS, and information in the Warning and Precautions section advising prescribers of the importance of measuring serum testosterone concentration if abuse is suspected.[48]

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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."[1]

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."[2]

Normal Calcium Values

Normal calcium blood values range: 8.5 to 10.2 mg/dL; may vary slightly among laboratories.[3]

Gender Dysphoria

Gender Dysphoria (previously named Gender Identity Disorder, sometimes used synonymously withTranssexualism) refers to "discomfort or distress that is caused by a discrepancy between a person's gender identity and that person's sex assigned at birth (and the associated gender role and/or primary and secondary sex characteristics)."[1] Distress can be severe, resulting in higher prevalence of depression and anxiety.[4–8] Global prevalence is difficult to ascertain, but recent estimates approximate that transgender people make up 0.3%-0.5% of the total U.S. population.[9] Treatment for gender dysphoria varies based on individualized assessment for each patient, but generally includes some combination of psychotherapy, cross-sex hormonal therapy, and sometimes surgical intervention.[4,5,10–13] The goals of treatment for Gender Dysphoria are to minimize dysphoria and help patients function in society in their desired gender role.[14]

The World Professional Association for Transgender Health (WPATH) established criteria for hormone therapy for patients with gender dysphoria. Hormone therapy must be individualized based on a patient's goals, the risk/benefit ratio of medications, the presence of other medical conditions, and consideration of social and economic issues. Hormone therapy can provide significant comfort to patients who do not wish to make a social gender role transition or undergo surgery, or who are unable to do so.

WPATH guidelines advise that initiation of hormone therapy may be undertaken after a psychosocial assessment has been conducted and informed consent has been obtained by a qualified health professional.

The WPATH criteria for hormone therapy are as follows:

1. Persistent, well-documented gender dysphoria;

2. Capacity to make a fully informed decision and to consent for treatment;
3. Age of majority in a given country
4. If significant medical or mental health concerns are present, they must be reasonably well controlled. The presence of co-existing mental health concerns does not necessarily preclude access to feminizing/masculinizing hormones; rather, these concerns need to be managed prior to or concurrent with treatment of gender dysphoria.[15]

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The purpose of Blue Cross and Blue Shield of Alabama's pharmacy policies are to provide a guide to coverage. Pharmacy policies are not intended to dictate to physicians how to practice medicine. Physicians should exercise their medical judgment in providing the care they feel is most appropriate for their patients.

Neither this policy, nor the successful adjudication of a pharmacy claim, is guarantee of payment.