### FDA APPROVED INDICATIONS AND DOSAGE

#### Topical Androgen Agents

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<th>Agent</th>
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| **Androderm®**<br>(testosterone 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, orchectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals.  
- Hypogonadotrophic hypogonadism (congenital or acquired): idiopathic gonadotropin or luteinizing hormone-releasing hormone (LH/RH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. | Hypogonadism  
2 mg/day and 4 mg/day system  
- 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)  
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  
- 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 |
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| **Axiron® (testosterone soln)**<br>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)**<br>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)**<br>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)**<br>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. |  |
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<tr>
<td><strong>Vogelxo™/Testosterone</strong></td>
<td>For testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:</td>
<td>1% gel:&lt;br&gt;-Initial dose is 50 mg testosterone (5 gm gel) once daily at the same time each day.&lt;br&gt;-Dose may be increased to 100 mg daily based on measured serum testosterone levels.&lt;br&gt;-The maximum recommended dose is 100 mg once daily.</td>
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<tr>
<td>1% gel</td>
<td>-Primary hypogonadism&lt;br&gt;-Hypogonadotrophic hypogonadism (congenital or acquired)</td>
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<tr>
<td><strong>Bio-T-Gel™</strong></td>
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<td>1% gel:&lt;br&gt;-Initial dose is 50 mg testosterone (5 gm gel) once daily in the morning.&lt;br&gt;-Dose may be increased to 75 mg and 100 mg daily based on measured serum testosterone levels.&lt;br&gt;-If serum testosterone level exceeds normal range at 50 mg dose, therapy should be discontinued.</td>
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<tr>
<td>(testosterone gel)</td>
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<tr>
<td>1% gel</td>
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### Oral Androgen and Anabolic Agents

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| **Android®** (methyltestosterone) | Males: Androgen replacement therapy related to the following:               | Males: -Androgen replacement therapy related to hypogonadism: 10 mg to 50 mg/day  
|                        |   -Primary hypogonadism (congenital or acquired) - testicular failure due to | -Androgen replacement therapy related to cryptorchidism: 10 mg 3 times daily  
|                        |   cryptorchidism, bilateral torsions, orchitis, vanishing testis syndrome;  | -Delayed puberty (adolescents only): 5 mg to 25 mg/day for a limited period, usually for 4 to 6 months  
|                        |   or orchidectomy - Hypogonadotropic hypogonadism (congenital or acquired) - | Females: -50 mg once daily up to four times/day  
|                        |   idiopathic gonadotropin or LHRH deficiency, or pituitary hypothalamic injury from tumors, trauma, or radiation | -If suitable response within 2-4 weeks, decrease to 25 mg two times daily  
|                        |   -Delayed puberty in males | **Females:**  
|                        | Females: Palliative treatment of breast cancer in women | **Females:**  
|                        | **Testred®** (methyltestosterone)                                           | **Females:**  
|                        | **Methitest®** (methyltestosterone)                                         | **Females:**  
|                        | 10 mg capsule b                                                              | **Females:**  
|                        | 10 mg tablet                                                                 | **Females:**  
|                        | Males: Androgen replacement therapy in male hypogonadism                     | **Females:**  
|                        | -Treatment of delayed puberty in males                                       | **Females:**  
|                        | **Androxy®** (fluoxymesterone)                                               | **Females:**  
|                        | **Anadrol-50®** (oxymetholone)                                               | **Females:**  
|                        | 10 mg tablet                                                                 | **Females:**  
|                        | Adults and children                                                         | **Females:**  
|                        | Treatment of anemias caused by deficient red cell production.                | **Females:**  
|                        | Acquired aplastic anemia, congenital aplastic anemia,  
|                        | myelofibrosis and the hypoplastic anemias due to the administration of myelotoxic drugs often respond | **Females:**  
|                        | Adults and children                                                         | **Females:**  
|                        | -1 to 5 mg/kg body weight per day.                                           | **Females:**  
|                        | -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 | **Females:**  
|                        | 50 mg tablet                                                                 | **Females:**  
|                        | Adults and children                                                         | **Females:**  
|                        | -1 to 5 mg/kg body weight per day.                                           |**Females:**  
|                        | -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 | **Females:**  
|                        | 10 mg - 40 mg per day in divided doses. Treatment should continue at least 2-3 months | **Females:**  

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## Oral Androgen and Anabolic Agents

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| danazol     | - 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. |
| [Danocrine®]a| 50 mg, 100 mg, 200 mg capsule                                                  |                                                                                          |
| Oxandrin®   | - 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 |
| (oxandrolone)b| 2.5 mg, 10 mg tablet                                                          |                                                                                          |

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## Injectable Androgen Agents

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| Delatestryl® (testosterone enanthate)²,³    | **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  
- Hypogonadotrophic 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/m² IM monthly until growth rate falls to prepubertal levels.  
    - Terminal growth phase: 100 mg/m² IM monthly until growth ceases  
    - Maintenance of virilization: 100 mg/m² IM twice monthly  
  - Delayed puberty: 50 mg to 200 mg IM every 2 to 4 weeks for a limited duration, for example, 4 to 6 months or 40 mg to 50 mg/m²/dose IM monthly for 6 months  
**Females:**  
- Palliation of inoperable breast cancer: 200 mg to 400 mg IM every 2 to 4 weeks |
| Depo-Testosterone® (testosterone cypionate)² | 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.  
- Hypogonadotrophic 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 |
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| Testopel® (testosterone pellets) | Males: -Primary hypogonadism (congenital or acquired): testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome; or orchiectomy  
| 75 mg                        | -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  
|                              |                                                                             | o For every 75 mg/week of testosterone propionate, 150 mg (2 pellets) should be implanted every 3—6 months  
|                              |                                                                             | -Delayed puberty (adolescents only): 150 mg to 450 mg (2-6 pellets) inserted subcutaneously by a healthcare professional every 3 to 6 months, although the lower end of the dosing range is typically sufficient  
|                              |                                                                             | • Treatment is usually only required for 4—6 months  
|                              |                                                                             | • Dosage is based on the minimal daily requirements of testosterone propionate determined by a gradual reduction of the amount administered parenterally  
|                              |                                                                             | For every 75 mg/week of testosterone propionate, 150 mg (2 pellets) should be implanted every 3—6 months  
| Aveed™ (testosterone undecanoate) | -Primary hypogonadism (congenital or acquired): testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome; or orchiectomy  
| 250 mg/mL                    | -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.  |

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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. Signs and symptoms 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 Endocrine Society Clinical Practice Guidelines (2010): Testosterone Therapy in Adult Men with Androgen Deficiency Syndromes recommends the following:12

- Initiate testosterone therapy with any of the following regimens, chosen on the basis of the patient’s preference, consideration of pharmacokinetics, treatment burden, and cost.
  - 75–100 mg of testosterone enanthate or cypionate administered intramuscularly (IM) weekly, or 150–200 mg administered every 2 weeks.
  - One or two 5-mg nongenital, testosterone patches applied nightly over the skin of the back, thigh or upper arm, away from pressure areas.
  - 5–10 g of a 1% testosterone gel applied daily over a covered area of nongenital skin (patients should wash hands after application).
  - 30 mg of a bioadhesive buccal testosterone tablet applied to buccal mucosa every 12 hours.

Endocrine Society Guidelines also state that when hypogonadal men were treated with oral testosterone, there was no increase in functional mobility or muscle strength compared with placebo. The oral formulations (17-α-methyltestosterone) should not be used in treatment of androgen deficiency due to variable response rates and risk of liver toxicity.12

The International Society of Andrology (ISA), the International Society for the Study of the Aging Male (ISSAM), the European Association of Urology (EAU), the European Academy of Andrology (EAA), and the American Society of Andrology (ASA) consensus statement on "Investigation, Treatment, and Monitoring of Late-Onset Hypogonadism" includes the following recommendations:13
Currently available intramuscular, subdermal, transdermal, oral, and buccal preparations of testosterone are safe and effective. The treating physician should have sufficient knowledge and adequate understanding of the pharmacokinetics as well as of the advantages and drawbacks of each preparation. The selection of the preparation should be a joint decision of an informed patient and physician.

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. 45

**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.49

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.44

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.43

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.43
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).34

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. 35

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 system17, testosterone enanthate18,19,22, oxandrolone20,21, and cypionate48. The use of topical testosterone to treat AIDS wasting in women is supported by several studies.30,31 Oxandrolone was studied in both male and female pediatric patients.21 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).16 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 ≥ 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.23 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.24

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.25 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. 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.

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.

The Endocrine Society recommends the following for the diagnosis and treatment of gender identity disorder (GID):

- It is recommended that a diagnosis of GID be made by a mental health professional (MHP). For children and adolescents, the MHP must also be training in child and adolescent developmental psychopathology
- Due to the high rate of remission of GID after the onset of puberty, complete social role change and hormone treatment in prepubertal children with GID is not recommended
- Adults and adolescents should meet eligibility and readiness criteria before hormone therapy:
  - Adults are eligible for cross-sex hormone treatment if they meet all of the below:
    - Fulfill DSM or ICD-10 criteria for GID or transsexualism
    - Do not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment
    - Demonstrate knowledge and understanding of the expected outcomes of hormone treatment, as well as medical and social risks and benefits
    - Have experienced a documented real life experience (RLE) of at least 3 months duration OR had a period of psychotherapy (duration specified by the MHP after the initial evaluation, usually a minimum of 3 months)
  - Adults and adolescents should fulfill the following readiness criteria before the cross-sex hormone treatment:
    - Has had further consolidation of gender identity during a RLE or psychotherapy
    - Has made some progress in mastering other identified problems leading to improvement or continuing stable mental health
    - Is likely to take hormones in a responsible manner
  - Adolescents are eligible and ready for GnRH treatment if they meet all of the following:
    - Fulfill DSM or ICD-10 criteria for GID or transsexualism
    - Have experienced puberty to at least Tanner stage 2
    - Have (early) pubertal changes that have resulted in an increase of their gender dysphoria
    - Do not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment
    - Have adequate psychological and social support during treatment
    - Demonstrate knowledge and understanding of the expected outcomes of GnRH analog treatment, cross-sex hormone treatment, and sex reassignment surgery, as well as medical and the social risks and benefits of sex reassignment
  - Adolescents are eligible for cross-sex hormone treatment if they meet all of the following:
    - Fulfill the criteria for GnRH treatment
• Are 16 years or older
• For adults, a treating endocrinologist should confirm the diagnostic criteria of GID or transsexualism and the eligibility and readiness criteria for the endocrine phase of gender transition
• Medical conditions that can be exacerbated by hormone depletion and cross-sex hormone treatments should be evaluated and addressed before initiation of treatment
• All transsexual individuals should be informed and counseled regarding option for fertility before initiation or puberty suppression in adolescents and before treatment with sex hormones of the desired sex in both adolescents and adults

The Endocrine Society also suggests the following for the diagnosis and treatment of gender identity disorder (GID):52
• The pubertal development of the desired, opposite sex should be initiated at about the age of 16 yr, using a gradually increasing dose schedule of cross-sex steroids
  o If the patient is relatively short, one may treat with oxandrolone, a growth-stimulating anabolic steroid
• Evaluate for cardiovascular risk factors in transsexual persons treated with hormones
• Conduct regular clinical and laboratory monitoring every 3 months during the first year and then once or twice yearly
• The following monitoring are suggested for FTM transsexual persons on cross-hormone therapy:
  o Evaluate patient every 2-3 months in the first year and then 1-2 times per year to monitor for appropriate signs of virilization and for development of adverse reactions
  o Measure serum testosterone every 2-3 months until levels are in the normal physiological male range
    ▪ For testosterone enanthate/cypionate injections, the testosterone level should be measured midway between injections. If the level is >700 ng/dL or <350 ng/dL, adjust dose accordingly
    ▪ For parenteral testosterone undecanoate, testosterone should be measured just before the next injection
    ▪ For transdermal testosterone, the testosterone level can be measured at any time after 1 week
    ▪ For oral testosterone undecanoate, the testosterone level should be measured 3-5 hours after ingestion
  o During the first 9-13 months of testosterone treatment, total testosterone levels may be high, although free testosterone levels are normal, due to high SHBG levels in some biological women
  o Measure estradiol levels during the first 6 months of testosterone treatment or until there has been no uterine bleeding for 6 months. Estradiol levels should be <50pg/mL
  o Measure complete blood count and liver function tests at baseline and every 3 months for the first year and then 1-2 times a year. Monitor weight, blood pressure, lipids, fasting blood sugar (if family history of diabetes), and hemoglobin A1c (if diabetic) at regular visits
  o Consider bone mineral density (BMD) testing at baseline if risk factors for osteoporotic fracture are present (e.g. previous fracture, family history, glucocorticoid use, prolonged hypogonadism). In individuals at low risk, screening for osteoporosis should be conducted at age 60 and in those who are not compliant with hormone therapy
    o If cervical tissue is present, an annual pap smear is recommended
    o If mastectomy is not performed, then consider mammograms
• Evaluate the risks and benefits of including a total hysterectomy and oophorectomy as part of sex reassignment surgery for FTM transsexual persons
Generally, transdermal testosterone, parenteral testosterone, and oral testosterone undecenoate can be used in FTM transition. Other forms of testosterone (e.g. implantable and buccal) are also available.52,53

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.14 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.15 Anabolic steroids are mainly abused by males and athletes to increase muscle mass and improve athletic performance.

Since the possible development of an adverse event during treatment (especially elevated hematocrit or prostate carcinoma) requires rapid discontinuation of testosterone substitution, short-acting preparations may be preferred over long-acting depot preparations in the initial treatment of patients with late onset hypogonadism.13

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.36

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.47

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.51

For additional clinical information see Prime Therapeutics Formulary Chapter 4.2: Androgens/Anabolic Steroids.

REFERENCES


41. Critical appraisal of androgen use in hereditary angioedema; a systemic review. Annals of Allergy, Asthma, & Immunology. 2015;114: 281-288


ADDITIONAL INFORMATION
Definition of HIV Wasting Syndrome
The World Health Organization (WHO) clinical diagnosis of HIV wasting syndrome consists of "unexplained 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

ADDITIONAL INFORMATION REFERENCES
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 two preferred topical androgen agents 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 two 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 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 non-preferred topical agents.

TARGET AGENTS
Topical Androgen Agents:
  Preferred Agents
  AndroGel® 1.62% (testosterone gel 1.62%)
  Axiron® (testosterone solution)
  Non-preferred Agents
  AndroGel® 1% (testosterone gel 1%)b
  Androderm® (testosterone transdermal system)
  Bio-T-Gel™ (testosterone gel)e
  Fortesta™ (testosterone gel)
  Natesto™ (testosterone nasal gel)
  Striant® (testosterone buccal system)
  Testim® (testosterone gel)
  Testosterone (testosterone gel)
  Vogelxo™ (testosterone gel)
  Stand-alone Agents
  testosterone gel 1% [generic AndroGel]

Injectable Androgen Agents:
  Avede™ (testosterone undecanoate)
  Delatrestyl® (testosterone enanthate)a,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)
- **Dianabol®**
- **Danazol** [Danocrine®]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

<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><strong>Topical Androgen Agents</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Androderm</strong>® (testosterone transdermal system)</td>
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<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>
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<tr>
<td>4 mg/day transdermal system</td>
<td>23100030008510</td>
<td>1 patch</td>
<td>M, N, O, or Y</td>
</tr>
</tbody>
</table>

| **AndroGel® / Testosterone (testosterone gel)** | | | |
| 1% gel, 25 mg/2.5 gm packetb | 23100030004025 | 2 packets | M, N, O, or Y |
| 1% gel, 50 mg/5 gm packetb | 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 gm/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) | | | |
| 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/dayc (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)** | | | |
| 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 |
### Injectable Androgen Agents

**Aveed™ (testosterone undeconoate)**
- 250 mg/mL, 3 mL vial
  - GPI: 23100030802030
  - Quantity Per Day Limit: 1 vial/28 days
  - Multisource Code: M, N, O, or Y

**Delatratryl® (testosterone enanthate)**
- 200 mg/mL, 5 mL multiple dose vial
  - GPI: 23100030202010
  - Quantity Per Day Limit: 1 vial/28 days
  - Multisource Code: M, N, O, or Y

**Depo-Testosterone® (testosterone cypionate)**
- 100 mg/mL, 10 mL multiple dose vial
  - GPI: 23100030102010
  - Quantity Per Day Limit: 1 vial/28 days
  - Multisource Code: M, N, O, or Y
- 200 mg/mL, 10 mL multiple dose vial
  - GPI: 23100030102015
  - Quantity Per Day Limit: 10 vials/28 days
  - Multisource Code: M, N, O, or Y

**Testopel® (testosterone pellets)**
- 75 mg
  - GPI: 23100030008920
  - Quantity Per Day Limit: 6 pellets/90 days
  - Multisource Code: M, N, O, or Y

### TARGET AGENTS – ORAL ANDROGENS AND ANABOLIC STEROIDS

<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><strong>Oral Androgen Agents</strong></td>
<td></td>
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<td></td>
</tr>
<tr>
<td><strong>Android® (methyltestosterone)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10 mg capsule</td>
<td>23100020000105</td>
<td></td>
<td>M, N, O, or Y</td>
</tr>
<tr>
<td><strong>Androxy® (fluoxymesterone)</strong></td>
<td></td>
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<td></td>
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<tr>
<td>10 mg tablet</td>
<td>23100010000315</td>
<td></td>
<td>M, N, O, or Y</td>
</tr>
<tr>
<td><strong>Methitest® (methyltestosterone)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10 mg tablet</td>
<td>23100020000105</td>
<td></td>
<td>M, N, O, or Y</td>
</tr>
<tr>
<td><strong>Testred® (methyltestosterone)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10 mg capsule</td>
<td>23100020000105</td>
<td></td>
<td>M, N, O, or Y</td>
</tr>
</tbody>
</table>

| **Anabolic Steroid Agents**      |                 |                                      |                  |
| **Anadrol-50® (oxymetholone)**   |                 |                                      |                  |
| 50 mg tablet                     | 23200050000320  |                                      | M, N, O, or Y    |
| **Danazol [Danocrine®]**         |                 |                                      |                  |
| 50 mg capsule                    | 23100050000105  |                                      | M, N, O, or Y    |
| 100 mg capsule                   | 23100050001110  |                                      | M, N, O, or Y    |
| 200 mg capsule                   | 23100050001115  |                                      | M, N, O, or Y    |
| **Oxandrin® (oxandroline)**      |                 |                                      |                  |
| 2.5 mg capsule                   | 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. 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
      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
   b. ALL of the following:
      i. Patient has primary or secondary (hypogonadotropic) hypogonadism
      AND
      ii. For patients not currently receiving testosterone replacement therapy, 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 has is not currently receiving testosterone replacement therapy AND 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. Patient has primary or secondary (hypogonadotropic) hypogonadism
            AND
            ii. For patients not currently receiving testosterone replacement therapy, 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 has is not currently receiving testosterone replacement therapy AND 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) or gender dysphoria, is initiating cross-sex hormone treatment AND ALL of the following:
   i. ONE of the following:
      1. The patient is an adolescent and ALL of the following:
         a. The patient is not pre-pubescent
         AND
         b. The patient meets ALL of the eligible criteria for cross-sex hormone treatment:
            i. A mental health professional (MHP) with training in child and adolescent developmental psychopathology has confirmed the diagnosis through DSM V or ICD-10 criteria for GID, gender dysphoria, or transsexualism
            AND
            ii. Patient has experienced puberty to at least Tanner stage 2
            AND
            iii. Patient has (early) pubertal changes that have resulted in an increase of their gender dysphoria
            AND
            iv. Patient does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment
            AND
            v. Patient has adequate psychological and social support during treatment
            AND
            vi. Patient demonstrates knowledge and understanding of the expected outcomes of cross-sex hormone treatment as well as medical and social risks and benefits of sex reassignment
   OR
   2. The patient is an adult and ALL of the following:
      a. The patient meets ALL of the eligible criteria for cross-sex hormone treatment:
         i. BOTH an endocrinologist AND a mental health professional (MHP) has confirmed the diagnosis through DSM V or ICD-10 criteria for GID, gender dysphoria, or transsexualism
         AND
         ii. The patient does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment
         AND
iii. The patient demonstrates knowledge and understanding of the expected outcomes of hormone treatment, as well as the medical and social risks and benefits

**AND**

iv. The patient has experienced a documented real life experience (RLE) of at least 3 months duration OR has had a period of psychotherapy (duration specified by the MHP after the initial evaluation, usually a minimum of 3 months)

**AND**

ii. The patient meets ALL of the readiness criteria for cross-sex hormone treatment:

1. The patient has had further consolidation of gender identity during a RLE or psychotherapy

**AND**

2. The patient has had some progress in mastering other identified problems leading to improvement or continuing stable mental health

**AND**

3. The patient is likely to take hormones in a responsible manner

**AND**

iii. The patient has been counseled regarding the reversible and irreversible effects of cross-sex hormone treatment

**AND**

iv. The patient has been informed and counseled regarding options for fertility after treatment initiation

**AND**

v. The patient has had medical conditions that can be exacerbated by hormone depletion and cross-sex hormone treatment evaluated and addressed

**AND**

vi. The patient has the capacity to make a fully informed decision and to consent to treatment

**OR**

d. The patient has a gender identity disorder (GID) or gender dysphoria diagnosis and is currently on cross-sex hormone treatment and the following:

i. The prescriber has indicated the member is receiving routine monitoring of cross-sex hormone treatment efficacy and safety at least once yearly

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

   **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 two preferred topical androgen agents **OR**

      ii. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to two preferred topical androgen agents

   **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)
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

Delatestryl (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 diagnosis:
         1. 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/m² AND all other causes of weight loss have been ruled out
         OR
         2. The patient is an adolescent with delayed puberty
         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. For patients not currently receiving testosterone replacement therapy, prior to testosterone replacement therapy, the patient had sign/symptom of hypogonadism

      AND
      ii. If the diagnosis is AIDS/HIV wasting or delayed puberty is an adolescent, ONE of the following:
         1. The patient is male
         OR
         2. The prescriber has provided documentation that the requested agent is medically appropriate for the patient’s gender

      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) or gender dysphoria, is initiating cross-sex hormone treatment AND ALL of the following:
      i. ONE of the following:
         1. The patient is an adolescent and ALL of the following:
             a. The patient is not pre-pubescent
                AND
             b. The patient meets ALL of the eligible criteria for cross-sex hormone treatment:
                i. A mental health professional (MHP) with training in child and adolescent developmental psychopathology has confirmed the diagnosis through DSM V or ICD-10 criteria for GID, gender dysphoria, or transsexualism
                AND
                ii. Patient has experienced puberty to at least Tanner stage 2
                AND
                iii. Patient has (early) pubertal changes that have resulted in an increase of their gender dysphoria
                AND
                iv. Patient does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment
                AND
                v. Patient has adequate psychological and social support during treatment
                AND
                vi. Patient demonstrates knowledge and understanding of the expected outcomes of cross-sex hormone treatment as well as medical and social risks and benefits of sex reassignment
                OR
         2. The patient is an adult and ALL of the following:
            c. The patient meets ALL of the eligible criteria for cross-sex hormone treatment:
                i. BOTH an endocrinologist AND a mental health professional (MHP) has confirmed the diagnosis through DSM V or ICD-10 criteria for GID, gender dysphoria, or transsexualism
ii. The patient does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment  

AND  

iii. The patient demonstrates knowledge and understanding of the expected outcomes of hormone treatment, as well as the medical and social risks and benefits  

AND  

iv. The patient has experienced a documented real life experience (RLE) of at least 3 months duration OR has had a period of psychotherapy (duration specified by the MHP after the initial evaluation, usually a minimum of 3 months)  

AND  

ii. The patient meets ALL of the readiness criteria for cross-sex hormone treatment:  

1. The patient has had further consolidation of gender identity during a RLE or psychotherapy  

AND  

2. The patient has had some progress in mastering other identified problems leading to improvement or continuing stable mental health  

AND  

3. The patient is likely to take hormones in a responsible manner  

AND  

ii. The patient has been counseled regarding the reversible and irreversible effects of cross-sex hormone treatment  

AND  

iii. The patient has been informed and counseled regarding options for fertility after treatment initiation  

AND  

iv. The patient has had medical conditions that can be exacerbated by hormone depletion and cross-sex hormone treatment evaluated and addressed  

AND  

v. The patient has the capacity to make a fully informed decision and to consent to treatment  

OR  

d. The patient has a gender identity disorder (GID) or gender dysphoria diagnosis and is currently on cross-sex hormone treatment and the following:  

i. The prescriber has indicated the member is receiving routine monitoring of cross-sex hormone treatment efficacy and safety at least once yearly  

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

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)

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

1. ONE of the following:
   a. ALL of the following:
      i. The patient has primary or secondary (hypogonadotropic) hypogonadism
      AND
      ii. For patients not currently receiving testosterone replacement therapy, 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
         a. The patient has a diagnosis of gender identity disorder (GID) or gender dysphoria, is initiating cross-sex hormone treatment AND ALL of the following:
            i. ONE of the following:
               1. The patient is an adolescent and ALL of the following:
                  a. The patient is not pre-pubescent
                  AND
b. The patient meets ALL of the eligible criteria for cross-sex hormone treatment:
   i. A mental health professional (MHP) with training in child and adolescent developmental psychopathology has confirmed the diagnosis through DSM V or ICD-10 criteria for GID, gender dysphoria, or transsexualism
      **AND**
   ii. Patient has experienced puberty to at least Tanner stage 2
      **AND**
   iii. Patient has (early) pubertal changes that have resulted in an increase of their gender dysphoria
      **AND**
   iv. Patient does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment
      **AND**
   v. Patient has adequate psychological and social support during treatment
      **AND**
   vi. Patient demonstrates knowledge and understanding of the expected outcomes of cross-sex hormone treatment as well as medical and social risks and benefits of sex reassignment

OR

2. The patient is an adult and ALL of the following:
   a. The patient meets ALL of the eligible criteria for cross-sex hormone treatment:
      i. BOTH an endocrinologist AND a mental health professional (MHP) has confirmed the diagnosis through DSM V or ICD-10 criteria for GID, gender dysphoria, or transsexualism
         **AND**
      ii. The patient does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment
         **AND**
      iii. The patient demonstrates knowledge and understanding of the expected outcomes of hormone treatment, as well as the medical and social risks and benefits
         **AND**
      iv. The patient has experienced a documented real life experience (RLE) of at least 3 months duration OR has had a period of psychotherapy (duration specified by the MHP after the initial evaluation, usually a minimum of 3 months)
         **AND**
   ii. The patient meets ALL of the readiness criteria for cross-sex hormone treatment:
      1. The patient has had further consolidation of gender identity during a RLE or psychotherapy
         **AND**
2. The patient has had some progress in mastering other identified problems leading to improvement or continuing stable mental health
   AND
3. The patient is likely to take hormones in a responsible manner
   AND
   iii. The patient has been counseled regarding the reversible and irreversible effects of cross-sex hormone treatment
   AND
   iv. The patient has been informed and counseled regarding options for fertility after treatment initiation
   AND
   v. The patient has had medical conditions that can be exacerbated by hormone depletion and cross-sex hormone treatment evaluated and addressed
   AND
   vi. The patient has the capacity to make a fully informed decision and to consent to treatment
   OR
   b. The patient has a gender identity disorder (GID) or gender dysphoria diagnosis and is currently on cross-sex hormone treatment and the following:
      i. The prescriber has indicated the member is receiving routine monitoring of cross-sex hormone treatment efficacy and safety at least once yearly
   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
   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 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:** 12 months

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

1. ONE 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. For patients not currently receiving testosterone replacement therapy, prior to testosterone replacement therapy, the patient had sign/symptom of hypogonadism

**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**

3. Patient is an adolescent with delayed puberty
   **AND**

ii. **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**

b. The patient has a diagnosis of gender identity disorder (GID) or gender dysphoria, is initiating cross-sex hormone treatment **AND ALL of the following:**
   i. **ONE of the following:**
      1. The patient is an adolescent and **ALL of the following:**
         a. The patient is not pre-pubescent
            **AND**
         b. The patient meets **ALL of the eligible criteria for cross-sex hormone treatment:**
            i. A mental health professional (MHP) with training in child and adolescent developmental psychopathology has confirmed the diagnosis through DSM V or ICD-10 criteria for GID, gender dysphoria, or transsexualism
               **AND**
            ii. Patient has experienced puberty to at least Tanner stage 2
               **AND**
iii. Patient has (early) pubertal changes that have resulted in an increase of their gender dysphoria AND
iv. Patient does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment AND
v. Patient has adequate psychological and social support during treatment AND
vi. Patient demonstrates knowledge and understanding of the expected outcomes of cross-sex hormone treatment as well as medical and social risks and benefits of sex reassignment

OR

2. The patient is an adult and ALL of the following:
   a. The patient meets ALL of the eligible criteria for cross-sex hormone treatment:
      i. BOTH an endocrinologist AND a mental health professional (MHP) has confirmed the diagnosis through DSM V or ICD-10 criteria for GID, gender dysphoria, or transsexualism AND
      ii. The patient does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment AND
      iii. The patient demonstrates knowledge and understanding of the expected outcomes of hormone treatment, as well as the medical and social risks and benefits AND
      iv. The patient has experienced a documented real life experience (RLE) of at least 3 months duration OR has had a period of psychotherapy (duration specified by the MHP after the initial evaluation, usually a minimum of 3 months)

   AND

   ii. The patient meets ALL of the readiness criteria for cross-sex hormone treatment:
      1. The patient has had further consolidation of gender identity during a RLE or psychotherapy AND
      2. The patient has had some progress in mastering other identified problems leading to improvement or continuing stable mental health AND
      3. The patient is likely to take hormones in a responsible manner AND

   iii. The patient has been counseled regarding the reversible and irreversible effects of cross-sex hormone treatment AND

   iv. The patient has been informed and counseled regarding options for fertility after treatment initiation AND
v. The patient has had medical conditions that can be exacerbated by hormone depletion and cross-sex hormone treatment evaluated and addressed

AND

vi. The patient has the capacity to make a fully informed decision and to consent to treatment

OR

c. The patient has a gender identity disorder (GID) or gender dysphoria diagnosis and is currently on cross-sex hormone treatment and the following:

i. The prescriber has indicated the member is receiving routine monitoring of cross-sex hormone treatment efficacy and safety at least once yearly

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

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 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)

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. For patients not currently receiving testosterone replacement therapy, 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

               2. BOTH of the following:
                  a. The patient has hypogonadism

                  AND

                  b. For patients not currently receiving testosterone replacement therapy, prior to testosterone replacement therapy, the patient had sign/symptom of hypogonadism
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 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**

b. The 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. BOTH of the following:
      i. ONE of the following:
1. The patient is female

2. The prescriber has provided documentation that the requested agent is medically appropriate for the patient’s gender

   a. Patient is a child or adolescent with Turner syndrome AND is currently receiving growth hormone

   b. Patient has weight loss following extensive surgery, chronic infections, or severe trauma

   c. Patient has chronic pain from osteoporosis

   d. Patient is on long-term administration of oral or injectable corticosteroids

   e. The patient has a diagnosis of gender identity disorder (GID) or gender dysphoria, is initiating cross-sex hormone treatment AND ALL of the following:

      i. ONE of the following:

         1. The patient is an adolescent and ALL of the following:

            a. The patient is not pre-pubescent

            b. The patient meets ALL of the eligible criteria for cross-sex hormone treatment:

               i. A mental health professional (MHP) with training in child and adolescent developmental psychopathology has confirmed the diagnosis through DSM V or ICD-10 criteria for GID, gender dysphoria, or transsexualism

               AND

               ii. Patient has experienced puberty to at least Tanner stage 2

               AND

               iii. Patient has (early) pubertal changes that have resulted in an increase of their gender dysphoria

               AND

               iv. Patient does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment

               AND

               v. Patient has adequate psychological and social support during treatment

               AND

               vi. Patient demonstrates knowledge and understanding of the expected outcomes of cross-sex hormone treatment as well as medical and social risks and benefits of sex reassignment

         2. The patient is an adult and ALL of the following:

            a. The patient meets ALL of the eligible criteria for cross-sex hormone treatment:

               i. BOTH an endocrinologist AND a mental health professional (MHP) has confirmed the diagnosis through DSM V or ICD-10 criteria for GID, gender dysphoria, or transsexualism

               AND
ii. The patient does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment

AND

iii. The patient demonstrates knowledge and understanding of the expected outcomes of hormone treatment, as well as the medical and social risks and benefits

AND

iv. The patient has experienced a documented real life experience (RLE) of at least 3 months duration OR has had a period of psychotherapy (duration specified by the MHP after the initial evaluation, usually a minimum of 3 months)

AND

   ii. The patient meets ALL of the readiness criteria for cross-sex hormone treatment:

      1. The patient has had further consolidation of gender identity during a RLE or psychotherapy

      AND

      2. The patient has had some progress in mastering other identified problems leading to improvement or continuing stable mental health

      AND

      3. The patient is likely to take hormones in a responsible manner

      AND

   iii. The patient has been counseled regarding the reversible and irreversible effects of cross-sex hormone treatment

      AND

   iv. The patient has been informed and counseled regarding options for fertility after treatment initiation

      AND

   v. The patient has had medical conditions that can be exacerbated by hormone depletion and cross-sex hormone treatment evaluated and addressed

      AND

   vi. The patient has the capacity to make a fully informed decision and to consent to treatment

OR

b. The patient has a gender identity disorder (GID) or gender dysphoria diagnosis and is currently on cross-sex hormone treatment and the following:

   i. The prescriber has indicated the member is receiving routine monitoring of cross-sex hormone treatment efficacy and safety at least once yearly

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