Androgens and Anabolic Steroids Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date **Date of Origin**
3/1/2023

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Anadrol-50® (oxymetholone) 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		13
Androderm® (testosterone) Transdermal patch system	For 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 syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. -Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. Limitations of use: -Safety and efficacy in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established -Safety and efficacy in males less than 18 years old have not been established		1
AndroGel®, Testosterone Gel*	For 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 syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. -Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation.	* – Generic available	2,3

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	Limitations of use: -Safety and efficacy in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established -Safety and efficacy in males less than 18 years old have not been established		
Aveed® (testosterone undecanoate) Injection	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		20
danazol* Capsule	-Endometriosis amenable to hormone management -Prevention of attacks of angioedema of all types	* – Generic available	14
Depo-Testosterone® (testosterone cypionate)* Injection	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 orchiectomy. -Hypogonadotropic hypogonadism (congenital or acquired) - idiopathic gonadotropin or LHRH deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. Limitations of use: -Safety and efficacy in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established	* – Generic available	18
Fortesta®, Testosterone Gel*	For 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 syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. -Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH)	* – Generic available	5

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	deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. Limitations of use: -Safety and efficacy in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established -Safety and efficacy in males less than 18 years old have not been established		
Jatenzo® (testosterone undecanoate) Capsule	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 syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. -Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation Limitations of use: Safety and efficacy in males less than 18 years old have not been established.		12
Kyzatrex™ (testosterone undecanoate) Capsules	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 syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle stimulating hormone (FSH), luteinizing hormone (LH)) above the normal range -Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low serum testosterone concentrations but have gonadotropins in the normal or low range. Limitations of use: Safety and efficacy in males less than 18 years old have not been established.		43
Methitest® (methyltestosterone) Tablet	-Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsions, orchitis, vanishing testis syndrome; or orchiectomy -Hypogonadotropic hypogonadism (congenital or acquired) - idiopathic gonadotropin or LHRH deficiency, or pituitary hypothalamic injury from tumors, trauma, or radiation -Delayed puberty in males -Palliative treatment of breast cancer in women		11

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Methyltestosterone Capsule	-Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsions, orchitis, vanishing testis syndrome; or orchiectomy -Hypogonadotropic hypogonadism (congenital or acquired) - idiopathic gonadotropin or LHRH deficiency, or pituitary hypothalamic injury from tumors, trauma, or radiation -Delayed puberty in males -Palliative treatment of breast cancer in women		10
Natesto® (testosterone) Nasal gel metered-dose pump	For 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 syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. -Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. Limitations of use: -Safety and efficacy in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established -Safety and efficacy in males less than 18 years old have not been established		6
Oxandrin® (oxandrolone) * 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	* – Generic available	15
Striant® (testosterone) Buccal system	For 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 syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. -Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation.		7

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Testim®, Testosterone Gel*	For 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 syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. -Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. Limitations of use: -Safety and efficacy in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established -Safety and efficacy in males less than 18 years old have not been established	* – Generic available	8
Testopel® (testosterone) Pellet	-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. -To stimulate puberty in carefully selected males with clearly delayed puberty Limitations of use: -Safety and efficacy in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established		19
testosterone enanthate* Injection	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 orchiectomy	* – Generic available	16

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Agent(s)	FDA Indication(s)	Notes	Ref#
	-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 <u>Females</u>: Metastatic mammary cancer: secondary use in women with advancing inoperable metastatic (skeletal) mammary cancer who are one to five years postmenopausal		
testosterone Topical solution*	For 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 syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. -Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. Limitations of use: -Safety and efficacy in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established -Safety and efficacy in males less than 18 years old have not been established	* - Generic available	4
Tlando™ (testosterone undecanoate) Capsule	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 syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. -Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation Limitations of use: Safety and efficacy in males less than 18 years old have not been established.		42

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Agent(s)	FDA Indication(s)	Notes	Ref#
Vogelxo®, Testosterone Gel*	For testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: -Primary hypogonadism (congenital or acquired) -Hypogonadotropic hypogonadism (congenital or acquired)	* – Generic available	9
Xyosted® (testosterone enanthate) Injection	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. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range. -Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range Limitations of Use: Safety and efficacy of Xyosted in males less than 18 years old have not been established		17

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Testosterone Deficiency	Testosterone is the predominant androgen in males and is involved in a multitude of physiological and biological processes throughout the body. The American Urological Association (AUA) recommends that clinicians use a total testosterone level below 300 ng/dL as a reasonable cut-off in support of the diagnosis of low testosterone. The clinical diagnosis of testosterone deficiency is only made when patients have low total testosterone levels combined with symptoms and/or signs. A challenge in making the diagnosis of testosterone deficiency is that many of the symptoms are non-specific and might be related to conditions other than low testosterone. Clinicians should conduct a targeted physical exam for signs that are associated with low testosterone. Signs and symptoms associated with testosterone deficiency include:(21)
	
	• Physical symptoms and signs:
	  ○ Reduced energy
	  ○ Reduced endurance
	  ○ Diminished work and/or physical performance
	  ○ Loss of body hair and/or reduced beard growth
	  ○ Very small testes (especially <6 ml)
	  ○ Fatigue
	  ○ Reduced lean muscle mass
	  ○ Obesity
	• Cognitive symptoms and signs:
	  ○ Depressive symptoms
	  ○ Cognitive dysfunction
	  ○ Reduced motivation
	  ○ Poor concentration
	  ○ Poor memory
	  ○ Irritability

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	• Sexual symptoms and signs:
	  ○ Reduced sex drive
	  ○ Erectile dysfunction
	
	The goal of testosterone therapy is the normalization of total testosterone levels combined with improvement in symptoms or signs. The AUA recommends that clinicians use the minimal dosing necessary to drive testosterone levels to the normal physiologic range of 450-600 ng/dL. Testosterone levels should be measured every 6-12 months while on testosterone therapy.(21)

Delayed Puberty	Delayed puberty in boys is the absence of testicular growth to at least 4 mL in volume or 2.5 cm in length by 14 years of age. Constitutional delay of growth and puberty is a common cause of delayed puberty; however, functional or persistent hypogonadism should be excluded. For more than 75% of patients with constitutional delay of growth and puberty, family history may reveal parental puberty delay. Boys older than 14 years with possible constitutional delay of growth and puberty may be offered jump-start therapy to induce puberty. Treating boys with testosterone for three to six months may accelerate attainment of final adult height and generally does not lead to premature epiphysis closure.(22)
Hereditary Angioedema (HAE)	C1-INH (C1 inhibitor) concentrate is the prophylaxis of choice for HAE. Attenuated androgens (e.g., danazol) have been recommended in the past, but frequent short courses may lead to long-term associated side effects. For scheduled pre-procedural prophylaxis, androgens are used for 5 days before and 2 to 3 days post event.(23)

Off Label Use ? AIDS/HIV	Men who are seropositive for HIV have been shown to have a higher rate of testosterone deficiency than the general population. It is postulated that the etiology of testosterone deficiency can be attributed to malnutrition, cytokine activity, opportunistic infections/acute illnesses, or the HIV medications themselves. HIV infected men who are testosterone deficient have also been shown to have concomitant elevated HbA1c levels and are at higher risk for CVD when compared to HIV-positive patients who have normal testosterone levels.(21) Weight loss and muscle wasting remain significant clinical problems, even in the era of potent antiviral therapy. Studies conducted in men on HAART (highly active antiretroviral therapy) show a 20% prevalence of hypogonadism among men with AIDS wasting. Treatment of associated opportunistic infections and optimization of antiretroviral therapy should be the first goal in patients with wasting. Clinical studies support the use of the following agents in men for AIDS/HIV-associated wasting syndrome: testosterone transdermal system(36), testosterone enanthate(37-39), oxandrolone(35,40) and testosterone cypionate.(41) Up to 60% of women suffering from AIDS wasting are androgen deficient.(24) The use of transdermal testosterone to treat AIDS wasting in women is supported by literature.(25,26) Oxandrolone was studied in both male and female pediatric patients.(35)
	
	The diagnosis of HIV wasting requires one of the following:(10)
	
	• Unintentional weight loss of greater than:
	  ○ 10% over 12 months
	  ○ 7.5% within 6 months
	• At least 5% total body cell mass (BCM) loss within 6 months
	• Body mass index (BMI) less than 20 kg/m^2
	• In men: BCM less than 35% of total body weight and BMI less than 27 kg/m^2
	• In women: BCM less than 23% of total body weight and BMI less than 27 kg/m^2

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Off Label Use - Turner Syndrome	The Turner Syndrome Consensus Group recommends oxandrolone for treatment of Turner syndrome, when used in conjunction with growth hormone (GH). Recommended dose of oxandrolone is 0.03 mg/kg/d and maintained below 0.05 mg/kg/d if the diagnosis of Turner Syndrome (and therefore GH treatment initiation) is delayed, and/or adult height outcome is likely to be unsatisfactory with the standard GH dose alone. If the decision is made to add oxandrolone, this should not be done until around 10 years.(28)
Off Label Use - Chronic Kidney Disease Anemia	The Kidney Disease Improving Global Outcomes (KDIGO) Clinical Practice Guideline for Anemia in Chronic Kidney Disease recommends not using androgens as an adjuvant to erythropoiesis stimulating agents. They cite the risks of androgen therapy and their uncertain benefit on hemoglobin concentration or clinical outcomes.(29)
Off Label Use - Vulvar Skin Disorder	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.(30) The Endocrine Society recommends against the generalized use of testosterone by women for infertility, sexual dysfunction (except for a specific diagnosis of hypoactive sexual desire disorder), cognitive dysfunction, cardiovascular dysfunction, metabolic dysfunction, bone health, or well-being. There are no clear indications for these uses, and evidence of safety in long-term studies is lacking.(31)
Off Label Use - Erectile Dysfunction	The American Urology Association (AUA) recommends that PDE5i (phosphodiesterase type 5 inhibitors) should be first-line therapy for erectile dysfunction. AUA also recommend that testosterone therapy is not an effective monotherapy for ED. If a man with ED has testosterone deficiency, he should be counseled that testosterone therapy in combination with a PDE5i is more likely to be effective than the PDE5i alone. There is insufficient data to address other combined treatments.(32)
Off Label Use - Myeloproliferative Neoplasms	Management of myelofibrosis associated anemia includes epoetin or darbepoetin for individuals with serum epoetin levels less than 500 mU/mL. Those with no response or loss of response should be managed as patients with serum epoetin greater than or equal to 500 mU/mL. Immunomodulatory agents (lenalidomide or thalidomide) with or without prednisone or danazol are recommended for the treatment of anemia in patients with serum epoetin levels greater than or equal to 500 mU/mL.(34)
Off Label Use - Gender Identity Disorder / Gender Dysphoria / Gender Incongruence	The Endocrine Society states the following for the diagnosis and treatment of gender identity disorder (GID) / gender dysphoria / gender incongruence:(33) • Recommend that a diagnosis of be made by a mental health professional (MHP). For children and adolescents, the MHP must also be training in child and adolescent developmental psychopathology • Recommend all transsexual individuals should be informed and counseled regarding option for fertility preservation prior to initiating puberty suppression in adolescents and prior to treating with hormonal therapy of the affirmed gender in both adolescents and adults • For the treatment of adolescents ○ Recommend for adolescents initiating treatment with sex hormones that the individual have sufficient mental capacity to give informed consent, which most adolescents have by age 16 ○ Recognize that there may be compelling reasons to initiate sex hormone treatment prior to the age of 16 years in some adolescents even though there are limited studies of gender-affirming hormone treatment administered before age 13.5 -14 years of age. ○ Suggest monitoring of clinical pubertal development every 3-6 months and laboratory parameters every 6-12 months during sex hormone treatment ○ Criteria for treatment with gender-affirming sex hormone therapy ▪ A qualified mental health professional has confirmed: • The persistence of gender dysphoria • Any coexisting psychological, medical, or social problems that could interfere with treatment (e.g. that may compromise treatment adherence) have been addressed, such that the adolescent's situation

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	and functioning are stable enough to start sex hormone treatment • The adolescent has sufficient mental capacity (which most adolescents have by age 16 year) to estimate the consequences of this (partly) irreversible treatment, weight the benefits and risks, and give informed consent to this (partly) irreversible treatment ▪ The adolescent: • Has been informed of the (irreversible) effects and side effects of treatment (including potential loss of fertility) and options to preserve fertility) • Has given informed consent and (particularly when the adolescent has not reached the age of legal medical consent, depending on applicable legislation) the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process ▪ A pediatric endocrinologist or other clinician experience in pubertal induction: • Agrees with the indication for sex hormone treatment • Has confirmed that there are no medical contraindications to sex hormone treatment • For the treatment of adults ○ Recommend clinicians evaluate and address medical conditions that can be exacerbated by hormone depletion and treatment with sex hormones before beginning treatment ○ Suggest clinicians measure hormone levels during treatment to ensure that endogenous sex steroids are suppressed and administered sex hormones are maintained in the normal physiologic range for the affirmed gender ○ Suggest regular clinical evaluation for physical changes and potential adverse changes in response to sex steroid hormones and laboratory monitoring of sex hormone levels every 3 months during the first year of hormone therapy for transgender males and females and then once or twice yearly ○ Criteria for treatment with gender-affirming hormone therapy ▪ Persistent, well-documented gender dysphoria/gender incongruence ▪ The capacity to make a fully informed decision and to consent for treatment ▪ The age of majority in a given country ▪ Mental health concerns, if present, must be reasonably well controlled Clinical studies have demonstrated the efficacy of several different androgen preparations to induce masculinization in transgender males, including parenteral testosterone enanthate, cypionate, and undecanoate, as well as transdermal testosterone.(33)
Safety	AndroGel testosterone solution, Fortesta, Testim, and Vogelxo carry a black box warning about secondary exposure to testosterone. • Virilization has been reported in children who were secondarily exposed to testosterone gel. • Children should avoid contact with unwashed or unclothed application sites in men using testosterone gel.

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	• Healthcare providers should advise patients to strictly adhere to recommended instructions for use.(2,4,5,8,9) Anadrol-50 and Oxandrin, carry a black box warning for several reasons. • Peliosis hepatitis, a condition in which liver and sometimes splenic tissue is replaced with blood-filled cysts, has been reported in patients receiving androgenic anabolic steroid therapy. These cysts are sometimes present with minimal hepatic dysfunction, but at other times they have been associated with liver failure. They are often not recognized until life-threatening liver failure or intra-abdominal hemorrhage develops. Withdrawal of drug usually results in complete disappearance of lesions. • Liver cell tumors are also reported. Most often these tumors are benign and androgen-dependent, but fatal malignant tumors have been reported. Withdrawal of drug often results in regression or cessation of progression of the tumor. However, hepatic tumors associated with androgens or anabolic steroids are much more vascular than other hepatic tumors and may be silent until life-threatening intra-abdominal hemorrhage develops. • Blood lipid changes that are known to be associated with increased risk of atherosclerosis are seen in patients treated with androgens and anabolic steroids. These changes include decreased high-density lipoprotein and sometimes increased low density lipoprotein. The changes may be very marked and could have a serious impact on the risk of atherosclerosis and coronary artery disease.(13) Aveed carries a black box warning concerning serious pulmonary oil microembolism (POME) reactions and anaphylaxis. • Serious POME reactions, involving urge to cough, dyspnea, throat tightening, chest pain, dizziness, and syncope; and episodes of anaphylaxis, including life-threatening reactions, have been reported to occur during or immediately after the administration of testosterone undecanoate injection. These reactions can occur after any injection of testosterone undecanoate during the course of therapy, including after the first dose. • Following each injection of Aveed, observe patients in the healthcare setting for 30 minutes in order to provide appropriate medical treatment in the event of serious POME reactions or anaphylaxis. • Aveed is available only through a restricted program called the Aveed REMS Program.(20) Danazol carries a black box warning for several reasons. • Use of danazol in pregnancy is contraindicated. A sensitive test (e.g., beta subunit test if available) capable of determining early pregnancy is recommended immediately prior to start of therapy. Additionally, a non-hormonal method of contraception should be us ed during therapy. If a patient becomes pregnant while taking danazol, administration of the drug should be discontinued, and the patient should be apprised of the potential risk to the fetus. Exposure to danazol in utero may result in androgenic effects on the female fetus; reports of clitoral hypertrophy, labial fusion, urogenital sinus defect, vaginal atresia, and ambiguous genitalia have been received (see PRECAUTIONS: Pregnancy, Teratogenic Effects).

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	• Thromboembolism, thrombotic and thrombophlebitic events including sagittal sinus thrombosis and life-threatening or fatal strokes have been reported. Experience with long-term therapy with danazol is limited. • Peliosis hepatis and benign hepatic adenoma have been observed with long-term use. Peliosis hepatis and hepatic adenoma may be silent until complicated by acute, potentially life-threatening intraabdominal hemorrhage. The physician therefore should be alert to this possibility. Attempts should be made to determine the lowest dose that will provide adequate protection. If the drug was begun at a time of exacerbation of hereditary angioneurotic edema due to trauma, stress or other cause, periodic attempts to decrease or withdraw therapy should be considered. • Danazol has been associated with several cases of benign intracranial hypertension also known as pseudotumor cerebri. Early signs and symptoms of benign intracranial hypertension include papilledema, headache, nausea and vomiting, and visual disturbances. Patients with these symptoms should be screened for papilledema and, if present, the patients should be advised to discontinue danazol immediately and be referred to a neurologist for further diagnosis and care.(14,15) Jatenzo, Kyzatrex, Tlando, and Xyosted carry a black box warning for blood pressure increases. • Can cause blood pressure (BP) increases that can increase the risk of major adverse cardiovascular events (MACE), including non-fatal myocardial infarction, non-fatal stroke and cardiovascular death. • Before initiating, consider the patient's baseline cardiovascular risk and ensure blood pressure is adequately controlled. • Periodically monitor for and treat new-onset hypertension or exacerbations of pre-existing hypertension and re-evaluate whether the benefits outweigh its risks in patients who develop cardiovascular risk factors or cardiovascular disease on treatment. • Due to this risk, use only for the treatment of men with hypogonadal conditions associated with structural or genetic etiologies.(12,17,43) For additional clinical information see Prime Therapeutics Formulary Chapter 4.2: Androgens/Anabolic Steroids.

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Number	Reference
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2	AndroGel 1% prescribing information. AbbVie Inc. May 2019.
3	AndroGel 1.62% prescribing information. AbbVie Inc. May 2019.
4	Testosterone solution pump prescribing information. Cipla USA, Inc. March 2019.
5	Fortesta prescribing information. Endo Pharma, Inc. May 2020.
6	Natesto Gel prescribing information. Aytu BioScience, Inc. October 2016.
7	Striant prescribing information. Endo Pharma, Inc. November 2016.
8	Testim prescribing information. Auxilium Pharma, Inc. May 2019.
9	Vogelxo prescribing information. Upsher-Smith Laboratories, Inc. May 2019.
10	Methyltestosterone capsule Prescribing Information. Amneal Pharmaceuticals, LLC. May 2019.
11	Methitest Prescribing Information. Amneal Pharmaceuticals, LLC. May 2019.
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POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Preferred Status	Effective Date
			M ; N ; O ; Y	N		
Anadrol-50	oxymetholone tab	50 MG	M ; N ; O ; Y	N		
Androderm	testosterone td patch	2 MG/24HR ; 4 MG/24HR	M ; N ; O ; Y	N		
Androgel ; Androgel pump ; Fortesta ; Natesto ; Testim ; Vogelxo ; Vogelxo pump	testosterone nasal gel ; testosterone td gel	1 % ; 1.62 % ; 10 MG/ACT ; 20.25 MG/1.25GM ; 25 MG/2.5GM ; 40.5 MG/2.5GM ; 5.5 MG/ACT ; 50 MG/5GM	M ; N ; O ; Y	M ; N ; O ; Y		
Aveed	testosterone undecanoate im inj in oil	750 MG/3ML	M ; N ; O ; Y	N		
	danazol cap	100 MG ; 200 MG ; 50 MG	M ; N ; O ; Y	Y		
Jatenzo ; Kyzatrex ; Tlando	testosterone undecanoate cap	100 MG ; 112.5 MG ; 150 MG ; 158 MG ; 198 MG ; 200 MG ; 237 MG	M ; N ; O ; Y	N		
Methitest	methyltestosterone oral tab	10 MG	M ; N ; O ; Y	N		
	methyltestosterone cap	10 MG	M ; N ; O ; Y	O ; Y		
	oxandrolone tab	10 MG ; 2.5 MG	M ; N ; O ; Y	O ; Y		
Testopel	Testosterone Implant Pellets 75 MG	75 MG	M ; N ; O ; Y	N		
Depo-testosterone	Testosterone Cypionate IM Inj in Oil 100 MG/ML	100 MG/ML	M ; N ; O ; Y	O ; Y		
Depo-testosterone	Testosterone Cypionate IM Inj in Oil 200 MG/ML	200 MG/ML	M ; N ; O ; Y	O ; Y		
	testosterone enanthate im inj in oil	200 MG/ML	M ; N ; O ; Y	N ; Y		
	testosterone td soln	30 MG/ACT	M ; N ; O ; Y	O ; Y		
Xyosted	testosterone enanthate solution auto-injector	100 MG/0.5ML ; 50 MG/0.5ML ; 75 MG/0.5ML	M ; N ; O ; Y	N		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date
			60.0	SYSTMS	30	Days				
Androderm	testosterone td patch	2 MG/24HR ; 4 MG/24HR	30.0	PATCHS	30	Days				

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Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date
Androgel pump	Testosterone TD Gel 20.25 MG/ACT (1.62%)	1.62 %	2.0	BOTTS	30	Days				
Androgel	Testosterone TD Gel 20.25 MG/1.25GM (1.62%)	20.25 MG/1.25 GM	30.0	PACKTS	30	Days				
Androgel	Testosterone TD Gel 25 MG/2.5GM (1%)	25 MG/2.5 GM	60.0	PACKTS	30	Days				
Androgel	Testosterone TD Gel 40.5 MG/2.5GM (1.62%)	40.5 MG/2.5 GM	60.0	PACKTS	30	Days				
Androgel ; Testim ; Vogelxo	Testosterone TD Gel 50 MG/5GM (1%)	1 % ; 50 MG/5GM	60.0	PACKTS	30	Days				
Aveed	Testosterone Undecanoate IM Inj in Oil 750 MG/3ML (250MG/ML)	750 MG/3ML	1.0	VIAL	28	Days				
Depo-testosterone	Testosterone Cypionate IM Inj in Oil 100 MG/ML	100 MG/ML	1.0	VIAL	28	Days				
Depo-testosterone	Testosterone Cypionate IM Inj in Oil 200 MG/ML	200 MG/ML	10.0	VIALS	28	Days				
Fortesta	Testosterone TD Gel 10MG/ACT (2%)	10 MG/ACT	2.0	BOTTS	30	Days				
Jatenzo	Testosterone Undecanoate Cap 158 MG	158 MG	120.0	CAPS	30	Days				
Jatenzo	Testosterone Undecanoate Cap 198 MG	198 MG	120.0	CAPS	30	Days				
Jatenzo	Testosterone Undecanoate Cap 237 MG	237 MG	60.0	CAPS	30	Days				
Kyzatrex	Testosterone Undecanoate Cap	100 MG	60.0	CAPS	30	Days				
Kyzatrex	Testosterone Undecanoate Cap	150 MG	120.0	CAPS	30	Days				
Kyzatrex	Testosterone Undecanoate Cap	200 MG	120.0	CAPS	30	Days				
Methitest	Methyltestosterone Oral Tab 10 MG	10 MG	600.0	TABS	30	Days				
	Methyltestosterone Cap 10 MG	10 MG	600.0	CAPS	30	Days				
Natesto	Testosterone Nasal Gel 5.5 MG/ACT	5.5 MG/ACT	3.0	PUMPS	30	Days				
Androgel ; Testim ; Vogelxo	Testosterone TD Gel 50 MG/5GM (1%)	1 % ; 50 MG/5GM	60.0	TUBES	30	Days				
Testopel	Testosterone Implant Pellets 75 MG	75 MG	6.0	PELLTS	90	Days				
Vogelxo pump	Testosterone TD Gel 12.5 MG/ACT (1%)	1 %	4.0	BOTTS	30	Days				
	testosterone enanthate im inj in oil	200 MG/ML	1.0	VIAL	28	Days				
	testosterone td soln	30 MG/ACT	2.0	BOTTS	30	Days				
Tlando	Testosterone Undecanoate Cap	112.5 MG	120.0	CAPS	30	Days				

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Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date
Vogelxo pump	Testosterone TD Gel 12.5 MG/ACT (1%)	1 %	4.0	BOTTS	30	Days				
Androgel ; Testim ; Vogelxo	Testosterone TD Gel 50 MG/5GM (1%)	1 % ; 50 MG/5GM	60.0	TUBES	30	Days				
Xyosted	Testosterone Enanthate Solution Auto-Injector 100 MG/0.5ML	100 MG/0.5 ML	2.0	MLS	28	Days				
Xyosted	Testosterone Enanthate Solution Auto-Injector 50 MG/0.5ML	50 MG/0.5 ML	2.0	MLS	28	Days				
Xyosted	Testosterone Enanthate Solution Auto-Injector 75 MG/0.5ML	75 MG/0.5 ML	2.0	MLS	28	Days				

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Anadrol-50	oxymetholone tab	50 MG	Commercial ; HIM ; ResultsRx
Androderm	testosterone td patch	2 MG/24HR ; 4 MG/24HR	Commercial ; HIM ; ResultsRx
Androgel ; Androgel pump ; Fortesta ; Natesto ; Testim ; Vogelxo ; Vogelxo pump	testosterone nasal gel ; testosterone td gel	1 % ; 1.62 % ; 10 MG/ACT ; 20.25 MG/1.25GM ; 25 MG/2.5GM ; 40.5 MG/2.5GM ; 5.5 MG/ACT ; 50 MG/5GM	Commercial ; HIM ; ResultsRx
Aveed	testosterone undecanoate im inj in oil	750 MG/3ML	Commercial ; HIM ; ResultsRx
	danazol cap	100 MG ; 200 MG ; 50 MG	Commercial ; HIM ; ResultsRx
Jatenzo ; Kyzatrex ; Tlando	testosterone undecanoate cap	100 MG ; 112.5 MG ; 150 MG ; 158 MG ; 198 MG ; 200 MG ; 237 MG	Commercial ; HIM ; ResultsRx
Methitest	methyltestosterone oral tab	10 MG	Commercial ; HIM ; ResultsRx
	methyltestosterone cap	10 MG	Commercial ; HIM ; ResultsRx
	oxandrolone tab	10 MG ; 2.5 MG	Commercial ; HIM ; ResultsRx
Testopel	Testosterone Implant Pellets 75 MG	75 MG	Commercial ; HIM ; ResultsRx
Depo-testosterone	Testosterone Cypionate IM Inj in Oil 100 MG/ML	100 MG/ML	Commercial ; HIM ; ResultsRx
Depo-testosterone	Testosterone Cypionate IM Inj in Oil 200 MG/ML	200 MG/ML	Commercial ; HIM ; ResultsRx
	testosterone enanthate im inj in oil	200 MG/ML	Commercial ; HIM ; ResultsRx
	testosterone td soln	30 MG/ACT	Commercial ; HIM ; ResultsRx
Xyosted	testosterone enanthate solution auto-injector	100 MG/0.5ML ; 50 MG/0.5ML ; 75 MG/0.5ML	Commercial ; HIM ; ResultsRx

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Androderm	testosterone td patch	2 MG/24HR ; 4 MG/24HR	Commercial ; HIM ; ResultsRx
Androgel pump	Testosterone TD Gel 20.25 MG/ACT (1.62%)	1.62 %	Commercial ; HIM ; ResultsRx

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Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Androgel	Testosterone TD Gel 20.25 MG/1.25GM (1.62%)	20.25 MG/1.25GM	Commercial ; HIM ; ResultsRx
Androgel	Testosterone TD Gel 25 MG/2.5GM (1%)	25 MG/2.5GM	Commercial ; HIM ; ResultsRx
Androgel	Testosterone TD Gel 40.5 MG/2.5GM (1.62%)	40.5 MG/2.5GM	Commercial ; HIM ; ResultsRx
Androgel ; Testim ; Vogelxo	Testosterone TD Gel 50 MG/5GM (1%)	1 % ; 50 MG/5GM	Commercial ; HIM ; ResultsRx
Aveed	Testosterone Undecanoate IM Inj in Oil 750 MG/3ML (250MG/ML)	750 MG/3ML	Commercial ; HIM ; ResultsRx
Depo-testosterone	Testosterone Cypionate IM Inj in Oil 100 MG/ML	100 MG/ML	Commercial ; HIM ; ResultsRx
Depo-testosterone	Testosterone Cypionate IM Inj in Oil 200 MG/ML	200 MG/ML	Commercial ; HIM ; ResultsRx
Fortesta	Testosterone TD Gel 10MG/ACT (2%)	10 MG/ACT	Commercial ; HIM ; ResultsRx
Jatenzo	Testosterone Undecanoate Cap 158 MG	158 MG	Commercial ; HIM ; ResultsRx
Jatenzo	Testosterone Undecanoate Cap 198 MG	198 MG	Commercial ; HIM ; ResultsRx
Jatenzo	Testosterone Undecanoate Cap 237 MG	237 MG	Commercial ; HIM ; ResultsRx
Kyzatrex	Testosterone Undecanoate Cap	100 MG	Commercial ; HIM ; ResultsRx
Kyzatrex	Testosterone Undecanoate Cap	150 MG	Commercial ; HIM ; ResultsRx
Kyzatrex	Testosterone Undecanoate Cap	200 MG	Commercial ; HIM ; ResultsRx
Methitest	Methyltestosterone Oral Tab 10 MG	10 MG	Commercial ; HIM ; ResultsRx
	Methyltestosterone Cap 10 MG	10 MG	Commercial ; HIM ; ResultsRx
Natesto	Testosterone Nasal Gel 5.5 MG/ACT	5.5 MG/ACT	Commercial ; HIM ; ResultsRx
Androgel ; Testim ; Vogelxo	Testosterone TD Gel 50 MG/5GM (1%)	1 % ; 50 MG/5GM	Commercial ; HIM ; ResultsRx
Testopel	Testosterone Implant Pellets 75 MG	75 MG	Commercial ; HIM ; ResultsRx
Vogelxo pump	Testosterone TD Gel 12.5 MG/ACT (1%)	1 %	Commercial ; HIM ; ResultsRx
	testosterone enanthate im inj in oil	200 MG/ML	Commercial ; HIM ; ResultsRx
	testosterone td soln	30 MG/ACT	Commercial ; HIM ; ResultsRx
Tlando	Testosterone Undecanoate Cap	112.5 MG	Commercial ; HIM ; ResultsRx
Vogelxo pump	Testosterone TD Gel 12.5 MG/ACT (1%)	1 %	Commercial ; HIM ; ResultsRx
Androgel ; Testim ; Vogelxo	Testosterone TD Gel 50 MG/5GM (1%)	1 % ; 50 MG/5GM	Commercial ; HIM ; ResultsRx
Xyosted	Testosterone Enanthate Solution Auto-Injector 100 MG/0.5ML	100 MG/0.5ML	Commercial ; HIM ; ResultsRx
Xyosted	Testosterone Enanthate Solution Auto-Injector 50 MG/0.5ML	50 MG/0.5ML	Commercial ; HIM ; ResultsRx
Xyosted	Testosterone Enanthate Solution Auto-Injector 75 MG/0.5ML	75 MG/0.5ML	Commercial ; HIM ; ResultsRx

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Prior Authorization with Quantity Limit - Through Generic	**Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. If the request is for Androderm, Androgel, Testosterone gel, testosterone solution, Fortesta, Natesto, Striant, Testim, or Vogelxo, the patient has a diagnosis of ONE of the following: 1. Primary or secondary (hypogonadotropic) hypogonadism **OR** 2. AIDS/HIV-associated wasting syndrome **OR** 3. Gender identity disorder (GID), gender dysphoria, or gender incongruence **OR** B. If the request is for Depo-Testosterone, testosterone enanthate, or Xyosted, the patient has a diagnosis of ONE of the following: 1. Primary or secondary (hypogonadotropic) hypogonadism **OR**

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Module	Clinical Criteria for Approval
	2. AIDS/HIV-associated wasting syndrome **OR** 3. Delayed puberty in an adolescent **OR** 4. Metastatic/inoperable breast cancer **OR** 5. Gender identity disorder (GID), gender dysphoria, or gender incongruence **OR** C. If the request is for Testopel, the patient has a diagnosis of ONE of the following: 1. Primary or secondary (hypogonadotropic) hypogonadism **OR** 2. Delayed puberty in an adolescent **OR** 3. Gender identity disorder (GID), gender dysphoria, or gender incongruence **OR** D. If the request is for Anadrol-50, the patient has a diagnosis of anemia **OR** E. If the request is for danazol, the patient has a diagnosis of ONE of the following: 1. Endometriosis amenable to hormone management **OR** 2. Angioedema and will be taking for the prevention of attacks **OR** 3. Myeloproliferative neoplasms **OR** 4. Fibrocystic breast disease **OR** F. If the request is for oxandrolone, the requested agent will be used for ONE of the following: 1. To promote weight gain **OR** 2. Bone pain frequently accompanying osteoporosis **OR** 3. AIDS/HIV-associated wasting syndrome **OR** 4. Turner syndrome **OR** 5. Gender identity disorder (GID), gender dysphoria, or gender incongruence **OR** G. If the request is for Jatenzo, Kyzatrex or Tlando, the patient has a diagnosis of primary or secondary (hypogonadotropic) hypogonadism **OR** H. If the request is for Aveed, the patient has a diagnosis of ONE of the following: 1. Primary or secondary (hypogonadotropic) hypogonadism **OR** 2. Gender identity disorder (GID), gender dysphoria, or gender incongruence **OR** I. If the request is for methyltestosterone or Methitest, the patient has a diagnosis of ONE of the following: 1. Primary or secondary (hypogonadotropic) hypogonadism **OR** 2. Metastatic/inoperable breast cancer **OR** 3. Delayed puberty in an adolescent **AND** 2. ONE of the following: A. If the request is for primary or secondary hypogonadism, then ONE of the following: 1. The patient is NOT currently receiving testosterone replacement therapy AND meets BOTH of the following: A. The patient has a sign or symptom of hypogonadism **AND** B. The patient has ONE of the following pretreatment levels: 1. Total serum testosterone level below the testing laboratory's normal range or is less than 300 ng/dL OR 2. Free serum testosterone level that is below the testing laboratory's normal range **OR** 2. The patient is currently receiving testosterone replacement therapy AND has ONE of the following current levels: A. Total serum testosterone level that is within OR below the testing laboratory's normal range OR is less than 300 ng/dL **OR** B. Free serum testosterone level that is within OR below the testing laboratory's normal range **OR** B. If the request is for AIDS/HIV-associated wasting syndrome, BOTH of the following: 1. ONE of the following: A. The patient has had an unintentional weight loss that meets ONE of the following: 1. 10% within 12 months **OR** 2. 7.5% within 6 months **OR** B. The patient has a body cell mass (BCM) loss greater than or equal to 5% within 6 months **OR**

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Module	Clinical Criteria for Approval
	C. The patient's sex is male and has BCM less than 35% of total body weight and body mass index (BMI) less than 27 kg/m^2 **OR** D. The patient's sex is female and has BCM less than 23% of total body weight and BMI less than 27 kg/m^2 **OR** E. The prescriber has provided information that the patient's BCM less than 35% or less than 23% and BMI less than 27 kg/m^2 are medically appropriate for diagnosing AIDS wasting/cachexia for the patient's sex **OR** F. The patient's BMI is less than 20 kg/m^2 **AND** 2. All other causes of weight loss have been ruled out **OR** C. If the request is for gender identity disorder (GID), gender dysphoria, or gender incongruence, ONE of the following: 1. The patient is an adolescent and ONE of the following: A. The patient is initiating sex hormone treatment AND ALL of the following: 1. A persistent diagnosis was confirmed by a mental health professional who is trained in child and adolescent developmental psychopathology **AND** 2. The patient's indication for sex hormone treatment has been confirmed by an endocrinologist OR clinician experienced in pubertal sex hormone induction **AND** 3. The patient does not have any medical contraindications to sex hormone treatment as confirmed by an endocrinologist OR clinician experienced in pubertal sex hormone induction **AND** 4. The patient has been informed and counseled regarding effects and side effects of sex hormone treatment including those which are irreversible, and regarding loss of fertility and options to preserve fertility **AND** 5. ONE of the following: A. The patient is 16 years of age or over **OR** B. The prescriber has provided information in support of initiating therapy prior to 16 years of age **AND** 6. The patient has sufficient mental capacity to give consent **AND** 7. The patient has provided consent AND, as applicable, the parents or other caretakers or guardians have provided consent to therapy **AND** 8. The patient's coexisting psychological, medical, or social problems that could interfere with treatment have been addressed and the patient's functioning is stable enough to start sex hormone therapy **OR** B. The patient is continuing therapy with sex hormone treatment AND the patient is being monitored at least once per year **OR** 2. The patient is an adult AND ONE of the following: A. The patient is initiating sex hormone treatment AND ALL of the following: 1. A persistent diagnosis has been confirmed by a mental health professional **AND** 2. The patient has sufficient mental capacity to give consent **AND** 3. The patient's coexisting mental health concerns, if present, are reasonably well controlled **AND** 4. The patient's medical conditions that can be exacerbated by treatment with sex hormones have been evaluated and addressed **OR** B. The patient is currently on sex hormone treatment and BOTH of the following: 1. ONE of the following:

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Module	Clinical Criteria for Approval

A. The patient's current testosterone level is ONE of the following:
   1. Total serum testosterone level that is within OR below the testing laboratory's normal range OR is less than 300 ng/dL **OR**
   2. Free serum testosterone level that is within OR below the testing laboratory's normal range **OR**

B. The prescriber has provided information in support of continuing therapy with the patient's current testosterone level **AND**

2. The patient is being monitored at least once per year **OR**

D. If the request is for delayed puberty in an adolescent, ONE of the following:
   1. The patient's sex is male **OR**
   2. The prescriber has provided information that the requested agent is medically appropriate for the patient's sex **OR**

E. If the request is for metastatic/inoperable breast cancer, ONE of the following:
   1. The patient's sex is female **OR**
   2. The prescriber has provided information that the requested agent is medically appropriate for the patient's sex **OR**

F. If the request is for anemia, the anemia is associated with ONE of the following:
   1. Deficient red cell production **OR**
   2. Acquired aplastic anemia **OR**
   3. Congenital aplastic anemia **OR**
   4. Myelofibrosis **OR**
   5. Hypoplastic anemia due to the administration of myelotoxic drugs **OR**

G. The request is for fibrocystic breast disease **OR**

H. The request is for endometriosis amenable to hormone management **OR**

I. The request is for the prevention of attacks of angioedema **OR**

J. If the request is for myeloproliferative neoplasms, ONE of the following:
   1. Patient has a serum EPO greater than or equal to 500 mU/mL **OR**
   2. Patient has a serum EPO less than 500 mU/mL and no response or loss of response to erythropoietic stimulating agents **OR**

K. If the request is for Turner syndrome, the agent will be used in conjunction with growth hormone (GH) **OR**

L. The request is for bone pain frequently accompanying osteoporosis **OR**

M. If the request is to promote weight gain, the patient has ONE of the following:
   1. weight loss following extensive surgery **OR**
   2. chronic infections **OR**
   3. severe trauma **OR**
   4. failure to gain or maintain normal weight without definite pathophysiologic reasons **OR**
   5. a prolonged administration of corticosteroids **AND**

3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**
4. If the request is for one of the following brand agents, then ONE of the following:

Brand Agent(s)
Androderm
Androgel
Fortesta
Natesto
Striant

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Module	Clinical Criteria for Approval

Testim
Testosterone
Vogelxo
Aveed
Depo-Testosterone
Testopel
Xyosted
Jatenzo
Kyzatrex
Tlando
Methitest

   A. The patient has tried and had an inadequate response to a generic androgen or anabolic steroid agent that is supported for use for the requested indication **OR**
   B. The patient has an intolerance or hypersensitivity to a generic androgen or anabolic steroid agent that is supported for use for the requested indication that is not expected to occur with the brand agent **OR**
   C. The patient has an FDA labeled contraindication to ALL generic androgen or anabolic steroid agents that is supported for use for the requested indication that is not expected to occur with the brand agent **AND**
5. ONE of the following:
   A. The patient will NOT be using the requested agent in combination with another androgen or anabolic steroid agent **OR**
   B. The prescriber has provided information in support of therapy with more than one androgen or anabolic steroid agent

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

NOTE: Quantity Limit applies, please refer to Quantity Limit Criteria section below.

Renewal Evaluation

Target Agent will be approved when ALL of the following are met:

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND**
2. The patient has had clinical benefit with the requested agent **AND**
3. ONE of the following:
   A. The patient has a diagnosis of primary or secondary hypogonadism and the patient's current testosterone level is ONE of the following:
      1. Total serum testosterone level that is within OR below the testing laboratory's normal range OR is less than 300 ng/dL **OR**
      2. Free serum testosterone level that is within OR below the testing laboratory's normal range **OR**

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Module	Clinical Criteria for Approval

B. The patient has a diagnosis of gender identity disorder (GID), gender dysphoria, or gender incongruence AND ONE of the following:
   1. If the patient is an adult, BOTH of the following:
      A. The patient is being monitored at least once per year **AND**
      B. ONE of the following:
         1. The patient's current testosterone level is ONE of the following:
            A. Total serum testosterone level that is within OR below the testing laboratory's normal range OR is less than 300 ng/dL **OR**
            B. Free serum testosterone level that is within OR below the testing laboratory's normal range **OR**
         2. The prescriber has provided information in support of continuing therapy with the patient's current testosterone level **OR**
   2. If the patient is an adolescent, the patient is being monitored at least once per year **OR**

C. The patient has a diagnosis other than primary or secondary hypogonadism, gender identity disorder (GID), gender dysphoria, or gender incongruence **AND**

4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**
5. If the request is for one of the following brand agents, then ONE of the following:

Brand Agent(s)
Androderm
Androgel
Fortesta
Natesto
Striant
Testim
Testosterone
Vogelxo
Aveed
Depo-Testosterone
Testopel
Xyosted
Jatenzo
Kyzatrex
Tlando
Methitest

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Module	Clinical Criteria for Approval
	A. The patient has tried and had an inadequate response to a generic androgen or anabolic steroid agent that is supported for use for the requested indication **OR** B. The patient has an intolerance or hypersensitivity to a generic androgen or anabolic steroid agent that is supported for use for the requested indication that is not expected to occur with the brand agent **OR** C. The patient has an FDA labeled contraindication to ALL generic androgen or anabolic steroid agents that is supported for use for the requested indication that is not expected to occur with the brand agent **AND** 6. ONE of the following: A. The patient will NOT be using the requested agent in combination with another androgen or anabolic steroid agent **OR** B. The prescriber has provided information in support of therapy with more than one androgen or anabolic steroid agent **Length of Approval:** 12 months NOTE: Quantity Limit applies, please refer to Quantity Limit Criteria section below.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested agent does NOT have a program quantity limit **OR** 2. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **OR** 4. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND** C. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval:** • Initial: 6 months (delayed puberty only), 12 months (all other indications) • Renewal: 12 months

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