Androgens and Anabolic Steroids Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date **Date of Origin**
02-01-2025

FDA LABELED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
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 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	2,3

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	• Topical testosterone products may have different doses, strengths, or application instructions that may result in different systemic exposure		
Aveed® (testosterone undecanoate) Intramuscular injection solution	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): 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		20
Azmiro™ (testosterone cypionate) Intramuscular injection solution	For testosterone replacement therapy in males 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, Klinefelter's 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 pediatric patients below the age of 12 years have not been established		13
danazol Capsule*	Endometriosis amenable to hormone management For hereditary angioedema, indicated for the prevention of attacks of angioedema of all types (cutaneous, abdominal, laryngeal) in males and females	*generic available	14
Depo®-Testosterone	For replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone:	*generic available	18

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(testosterone cypionate) Intramuscular injection solution*	• Primary hypogonadism (congenital or acquired): testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome; or orchiectomy • Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation Note: Safety and efficacy in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established		
Fortesta®, Testosterone Gel*	For replacement therapy in 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	5
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®, Undecatrex™ (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. These men usually have low serum testosterone		7,43

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	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.		
Methitest® (methyltestosterone) Tablet	Androgens are indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone in males: • Primary hypogonadism (congenital or acquired): testicular failure due to cryptorchidism, bilateral torsions, orchitis, vanishing testis syndrome; or orchiectomy • Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary hypothalamic injury from tumors, trauma, or radiation • Note: Safety and efficacy of methyltestosterone in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established Androgens may be used to stimulate puberty in carefully selected males with clearly delayed puberty Androgens may be used secondarily in women with advancing inoperable metastatic (skeletal) mammary cancer who are 1 to 5 years postmenopausal. This treatment has also been used in premenopausal women with breast cancer who have benefitted from oophorectomy and are considered to have a hormone-responsive tumor.		11
methyltestosterone Capsule*	Androgens are indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone in males: • Primary hypogonadism (congenital or acquired): testicular failure due to cryptorchidism, bilateral torsions, orchitis, vanishing testis syndrome; or orchiectomy • Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary hypothalamic injury from tumors, trauma, or radiation • Note: Safety and efficacy of methyltestosterone in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established Androgens may be used to stimulate puberty in carefully selected males with clearly delayed puberty Androgens may be used secondarily in women with advancing inoperable metastatic (skeletal) mammary cancer who are 1 to 5 years postmenopausal. This treatment has also been used in premenopausal	*generic available	10

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	women with breast cancer who have benefitted from oophorectomy and are considered to have a hormone-responsive tumor.		
Natesto® (testosterone) Nasal 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's 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
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's 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 • Topical testosterone products may have different doses, strengths, or application instructions that may result in different systemic exposure	*generic available	8
Testopel® (testosterone) Pellet	Androgens are indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone in males: • Primary hypogonadism (congenital or acquired): testicular failure due to cryptorchidism, bilateral torsions, orchitis, vanishing testis syndrome; or orchiectomy • Hypogonadotropic hypogonadism (congenital or acquired): gonadotropic luteinizing hormone-releasing hormone (LHRH)		19

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	deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation • Note: Safety and efficacy in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established Androgens may be used to stimulate puberty in carefully selected males with clearly delayed puberty		
Testosterone Enanthate Intramuscular injection solution	For replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone in males: • Primary hypogonadism (congenital or acquired): testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, or orchiectomy • Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation • Note: Safety and efficacy in men with age-related hypogonadism have not been established May be used to stimulate puberty in carefully selected males with clearly delayed puberty May be used secondarily in women with advancing inoperable metastatic (skeletal) mammary cancer who are one to five years postmenopausal. This treatment has also been used in premenopausal women with breast cancer who have benefited from oophorectomy and are considered to have a hormone-responsive tumor.		16
testosterone Topical solution*	For replacement therapy in 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): 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's		44

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	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.		
Vogelxo®, 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's 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. • Topical testosterone products may have different doses, strengths, or application instructions that may result in different systemic exposure.	*generic available	9
Xyosted® (testosterone enanthate) Subcutaneous injection solution	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:		17

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	• Safety and efficacy in males less than 18 years old have not been established		

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.(21) Testosterone deficiency caused by abnormalities at the testicular level is considered primary hypogonadism, while dysfunction of the hypothalamus or the pituitary is considered secondary hypogonadism.(27)
	
	Patients with testosterone deficiency have consistent low serum total testosterone and/or free testosterone levels. Reference ranges for testosterone levels vary among laboratories and assays due to a lack of standardization of assays, calibrator differences, and differences in the reference populations used.(27) Laboratories often define the normal value of their reference range as being within the 5th and 95th percentile of the sampled population. The American Urological Association (AUA) recommends that clinicians can use an absolute value of a total testosterone level below 300 ng/dL as a reasonable cut-off in support of the diagnosis of low testosterone. Clinicians may use the reference range of the laboratory or the recommended absolute measure to determine if a patient has low testosterone.(21)
	
	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.(21) Signs and symptoms associated with testosterone deficiency include:(21,27)
	
	• 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 less than 6 ml)
	  ○ Fatigue
	  ○ Reduced lean muscle mass
	  ○ Obesity
	• Cognitive symptoms and signs:
	  ○ Depressive symptoms
	  ○ Cognitive dysfunction
	  ○ Reduced motivation
	  ○ Poor concentration
	  ○ Poor memory
	  ○ Irritability
	• Sexual symptoms and signs:
	  ○ Reduced sex drive
	  ○ Erectile dysfunction
	
	Testosterone therapy is used to raise serum testosterone levels and treat testosterone deficiency. 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 total testosterone levels to the normal physiologic range, with an absolute value of 450-600 ng/dL being provided. Testosterone levels should be measured every 6-12 months while on testosterone therapy.(21)

Delayed Puberty	Delayed puberty in boys is defined as the absence of testicular growth to at least 4 mL in volume or 2.5 cm in length by 14 years of age. It should also be suspected if pubertal development stops or regresses. The most common cause of delayed puberty is a constitutional delay of growth and puberty (CDGP).(22) CDGP is a non-pathological condition that is an extreme variant in late pubertal timing, and it is usually seen in patients with a family history of delayed puberty.(30) Patients may present with short stature on examination, and a delayed bone age is supportive of the diagnosis.(22,30) Delayed puberty may also be caused by hypo- or hyper-gonadotropic hypogonadism (HH), but differentiating between one of these causes and CDGP can often be clinically challenging due to similar symptoms, signs, and lab results. A diagnosis of CDGP is one of exclusion, and determining the etiology of the patient's delayed puberty is important due to the difference in treatment regimens. Patients with a HH cause need to be treated for their underlying condition, with long term hormone replacement therapy potentially being needed.(30) For boys with CDGP, clinical observation and monitoring for signs of spontaneous puberty is the common approach.(30,31) Testosterone therapy for 3 to 6 months is recommended to initiate puberty for prepubertal boys 14 years of age or older with significant psychological distress (e.g., bullying, low self-esteem).(22,30) Once puberty starts, testosterone administration should be discontinued.(30,31) If puberty is not induced, testosterone therapy can be extended for an additional 3 to 6 months; it may also support a diagnosis of HH. Intramuscular testosterone enanthate or testosterone cypionate at low doses are used most frequently. Transdermal testosterone, subcutaneous testosterone enanthate, and other formulations used for adult testosterone replacement therapy have not been sufficiently studied to support their use for CDGP, and their fixed doses make them inappropriate for this population.(31)
Hereditary Angioedema (HAE)	Hereditary angioedema (HAE) is a rare genetic disease that is caused by a deficiency or dysfunction of C1-inhibitor protein (C1-INH). The disease manifests as angioedema of the skin, the abdomen, and/or the upper respiratory tract. Plasma derived C1-INH is the preferred first line agent for both short-term and long-term prophylactic treatment of HAE. Attenuated androgens (e.g., danazol) have historically been used for preprocedural prophylaxis and long-term prophylaxis, but the risk of androgenic and anabolic side effects limit their use, especially long term.(23) For short term prophylaxis prior to a medical, surgical, or dental procedure, danazol may be used for 5 days before and continued 2 to 5 days after the procedure. Danazol may also be used short term prior to a stressful life event that may induce an angioedema attack. Danazol is recommended as second line therapy for long term prophylaxis.(23,28) The use of danazol can be used if first-line medications (e.g., C1-INH, lanadelumab, berotralstat) are not available or if a patient requires oral therapy.(28) The minimal effective dose should be used due to the risk of side effects.(23)
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: Erectile Dysfunction	The majority of patients who present with erectile dysfunction (ED) have normal testosterone levels.(35) The recommended treatment for these patients is oral phosphodiesterase type 5 (PDE5) inhibitors.(32,36) There is no evidence of benefits in using testosterone therapy for ED in patients with normal testosterone levels, and it is recommended that testosterone therapy not be used.(36) The benefits of testosterone therapy for ED is related to the normalization of testosterone levels in patients with testosterone deficiency (TD), specifically.(36) Therefore, it is recommended that patients with TD and ED be treated with testosterone therapy to get their testosterone levels within normal limits (or greater than 300 ng/dL), and to use a PDE5 inhibitor in addition to testosterone therapy as add-on therapy for ED symptoms.(32)
Off Label Use: Myelofibrosis Associated Anemia	Danazol is a recommended regimen for myelofibrosis (MF) associated anemia in patients with no symptomatic splenomegaly and/or no constitutional symptoms and a

	serum erythropoietin (EPO) greater than or equal to 500 mU/mL (NCCN 2a recommended use). Patients who were previously treated with a erythropoietin stimulating agent (ESA) for MF associated anemia and had no response, or loss of response, should be managed as a patient with an EPO level greater than or equal to 500 mU/mL.(34)
Off Label Use: Gender Dysphoria / Gender Incongruence	Transgender and gender diverse (TGD) persons may seek support and medically necessary gender-affirming hormone therapy (GAHT) to meet their goals for gender identity and expression.(24) Sex steroids matching the individual's affirmed gender are used to achieve and maintain physiologic levels of hormones needed to meet these treatment goals.(24,33) Health care professionals (HCP) assessing TGD people for GAHT should have experience, or be qualified, to assess clinical aspects of gender dysphoria, incongruence, and diversity whenever possible and necessary. They should also be able to identify co-existing mental health or psychosocial concerns and be able to distinguish them from conditions that may be mistaken as gender incongruence. Ideally and where possible, HCPs should work with professionals from different disciplines for consultation, treatment management, and referral, if required. Other members of a multidisciplinary team may include a mental health professional (MHP) or an endocrinologist. The inclusion of a psychologist, psychiatrist, or other MHP is not required. Many TGD people will not require therapy or other forms of mental health care, while others may benefit. Individuals should not be referred for mental health treatment exclusively on the basis of a transgender identity.(24) However, to ensure continuity of care and minimize gaps in accessible care, a HCP without expertise may provide care and support the assessment for GAHT. Due to the importance of GAHT for TGD people, a lack of available experts and resources should not constitute a barrier to care.(24) An informed consent process is adequate for initiating GAHT.(25) Most medications used for GAHT are common and can be safely prescribed by primary care providers (PCP) or other non-specialists, and a specific certification is not required to prescribe them.(24,25) With that, TGD people should be supported to access care with an experienced HCP as soon as possible and should be referred to a MHP if needed.(24) HCPs should be able to assess capacity for the patient to consent to treatment. Consent requires the cognitive capacity to comprehend the nature of the treatment, understand the risks and benefits of a treatment, and the potential negative and positive outcomes. It also requires the ability of the patient to retain that information and use that understanding to make and communicate an informed decision.(24) Most adolescents have the capacity to give informed consent for GAHT by age 16.(33) However, the legal guardian(s) of a minor usually provides the consent for treatment and assent is provided from the minor in a parallel process through communication with the provider.(24) Prior to initiating GAHT, gender incongruence/dysphoria should be documented and sustained over time. The DSM-5 classification of gender dysphoria indicates there should be marked gender incongruence for a duration of at least 6 months. There is minimal evidence to define the length of persistence required for treatment in adults. HCPs should give due consideration to the life stage, history, and current circumstances of the adult being assessed, including the nature and consistency of gender incongruence. An abrupt or superficial change in gender identity or lack of persistence is insufficient to initiate GAHT.(24) For adolescents, due to potential shifts in gender-related experiences and the treatment having some irreversible effects, gender diversity/incongruence should have persisted for several years prior to initiating GAHT. A persistent diagnosis requires careful and extended assessments of the young person over time and enables a meaningful decision to be made regarding treatment. Evidence can include a history obtained directly from the adolescent and parents/caregivers when this information is not documented in the medical records.(24)

	For adults, the following should be met prior to initiating GAHT: • Gender incongruence is marked and sustained(24,33) • Demonstrates capacity to consent for the specific gender-affirming hormone treatment(24,33) • Other possible causes of apparent gender incongruence have been identified and excluded(24) • Mental health and physical/medical conditions that could negatively impact the outcome of treatment have been assessed, with risks and benefits discussed(24,33) • Understands the effects and side effects of gender-affirming hormone treatment, including effects on reproduction, and they have explored reproductive options(24,33) For adolescents, the following should be met prior to initiating GAHT: • The HCP has conducted a comprehensive biopsychosocial assessment, and included mental health and other medical professionals when required(24) • Involvement of parent(s)/guardian(s) in the assessment process, unless their involvement is determined to be harmful to the adolescent or not feasible(24,33) • Gender diversity/incongruence is marked and sustained over time(24,33) • Demonstrates the emotional and cognitive maturity required to provide informed consent/assent for treatment(24,33) • Mental health concerns (if any), physical/medical conditions, or social problems that may interfere with diagnostic clarity, capacity to consent, and gender-affirming medical treatments have been addressed; sufficiently so that gender-affirming medical treatment can be provided optimally(24,33) • Informed of the effects (including irreversible) and side effects of treatment; including reproductive effects and the potential loss of fertility and the available options to preserve fertility(24,33) • Patient is 16 years of age or older(24,33) o There may be compelling reasons to initiate GAHT prior to 16 years old, such as avoiding prolonged pubertal suppression due to potential bone health concerns or the psychosocial implications of delaying puberty.(24) However, there is limited information to initiate treatment prior to 13.5 to 14 years of age.(24,33) Providers should compare the physical and psychological benefits and risks of starting treatment versus delaying treatment.(24) o It is not recommended to start hormone therapy prior to the onset of endogenous puberty(24,33) Testosterone is used for the treatment of GAHT in patients seeking masculinizing treatment. Injectable preparations are often used, but transdermal formulations (e.g., gels, creams, patches) and subcutaneous pellets may also be considered.(24,25) Injectable testosterone may be given intramuscularly or subcutaneously.(25,33) Oral dosage forms of testosterone may also be used.(26) Patients receiving testosterone should be evaluated for physical changes and adverse effects, as well as having serum testosterone levels monitored, every 3 months during the first year of hormone therapy or with dose changes. Once the patient has attained a stable adult maintenance dose, and serum testosterone levels are in the normal physiologic male range, evaluation and monitoring should be conducted once or twice a year.(24,33) Dosing should be adjusted to target serum levels within the normal range for the individual's gender identity.(24)
Safety	AndroGel, Fortesta, Testim, testosterone solution, and Vogelxo carry a boxed warning about secondary exposure to testosterone:(2,3,4,5,8,9) • 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. • Healthcare providers should advise patients to strictly adhere to recommended instructions for use. Aveed carries a boxed warning concerning serious pulmonary oil microembolism (POME) reactions and anaphylaxis:(20) • 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. Danazol carries boxed warnings for:(14) • 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. • 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. Jatenzo, Kyzatrex, Tlando, Undecatrex, and Xyosted carry a boxed warning for blood pressure increases:(7,12,17,43,44) • 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. Androderm, Fortesta, Methitest, methyltestosterone capsules, Natesto, Testim, Testopel, testosterone solution, Vogelxo are contraindicated in:(1,4,5,6,8,9,10,11,19) • Men with carcinoma of the breast or known or suspected carcinoma of the prostate • Women who are pregnant AndroGel is contraindicated in:(2,3) • Men with carcinoma of the breast or known or suspected carcinoma of the prostate • Women who are pregnant o Pregnant women need to be aware of the potential for transfer of testosterone from men treated with AndroGel Aveed is contraindicated in:(20) • Men with carcinoma of the breast or known or suspected carcinoma of the prostate • Women who are pregnant • Men with known hypersensitivity to Aveed or any of its ingredients (testosterone undecanoate, refined castor oil, benzyl benzoate) Azmiro is contraindicated in:(13) • Patients with a known hypersensitivity to Azmiro or to any of its components • Men with carcinoma of the breast or known or suspected carcinoma of the prostate gland • Women who are pregnant Danazol is contraindicated in patients with:(14) • Undiagnosed abnormal genital bleeding • Markedly impaired hepatic, renal, or cardiac function • Pregnancy • Breast feeding • Porphyria • Androgen-dependent tumor • Active thrombosis or thromboembolic disease and history of such events • Hypersensitivity to danazol Depo-Testosterone is contraindicated in:(18) • Patients with a known hypersensitivity to the drug • Males with carcinoma of the breast • Males with known or suspected carcinoma of the prostate gland • Women who are pregnant • Patients with serious cardiac, hepatic or renal disease Jatenzo, Kyzatrex, Tlando, and Undecatrex are contraindicated in:(7,12,43,44)

	• Men with carcinoma of the breast or known or suspected carcinoma of the prostate • Women who are pregnant • Patients with known hypersensitivity to testosterone undecanoate or any ingredients in the product • Men with hypogonadal conditions, such as "age-related hypogonadism", that are not associated with structural or genetic etiologies Testosterone enanthate is contraindicated in:(16) • Men with carcinoma of the breast or known or suspected carcinoma of the prostate • Women who are or may become pregnant • Patients with a history of hypersensitivity to any of its components Xyosted is contraindicated in:(17) • Men with carcinoma of the breast or known or suspected carcinoma of the prostate • Women who are pregnant • Men with hypersensitivity to Xyosted or any of its ingredients (testosterone enanthate and sesame oil) • Men with hypogonadal conditions, such as "age-related hypogonadism", that are not associated with structural or genetic etiologies

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POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
	danazol cap	100 MG ; 200 MG ; 50 MG	M ; N ; O ; Y	Y		
	methyltestosterone cap	10 MG	M ; N ; O ; Y	Y		
Methitest	methyltestosterone oral tab	10 MG	M ; N ; O ; Y	N		
Depo-testosterone	Testosterone Cypionate IM Inj in Oil 100 MG/ML	100 MG/ML	M ; N ; O ; Y	Y		
Depo-testosterone	Testosterone Cypionate IM Inj in Oil 200 MG/ML	200 ; 200 MG/ML	M ; N ; O ; Y	Y		
Azmiro	testosterone cypionate im soln pref syringe in oil	200	M ; N ; O ; Y	N		
	testosterone enanthate im inj in oil	200 MG/ML	M ; N ; O ; Y	N		
Xyosted	testosterone enanthate solution auto-injector	100 MG/0.5ML ; 50 MG/0.5ML ; 75 MG/0.5ML	M ; N ; O ; Y	N		
Testopel	Testosterone Implant Pellets 75 MG	75 MG	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		
Androderm	testosterone td patch	2 MG/24HR ; 4 MG/24HR	M ; N ; O ; Y	N		
	testosterone td soln	30 MG/ACT	M ; N ; O ; Y	Y		
Jatenzo ; Kyzatrex ; Tlando ; Undecatrex	testosterone undecanoate cap	100 MG ; 112.5 MG ; 150 MG ; 158 MG ; 198 MG ; 200 MG ; 237 MG	M ; N ; O ; Y	M ; N		
Aveed	testosterone undecanoate im inj in oil	750 MG/3ML	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	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
			60	Systems	30	DAYS			
	Methyltestosterone Cap 10 MG	10 MG	600	Capsules	30	DAYS			

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
	testosterone enanthate im inj in oil	200 MG/ML	1	Vial	28	DAYS			
	Testosterone TD Gel 20.25 MG/1.25GM (1.62%)	20.25 MG/1.25 GM	30	Packets	30	DAYS			
	Testosterone TD Gel 40.5 MG/2.5GM (1.62%)	40.5 MG/2.5 GM	60	Packets	30	DAYS			
	testosterone td soln	30 MG/ACT	2	Bottles	30	DAYS			
Androderm	testosterone td patch	2 MG/24HR ; 4 MG/24HR	30	Patches	30	DAYS			
Androgel	Testosterone TD Gel 25 MG/2.5GM (1%)	25 MG/2.5 GM	60	Packets	30	DAYS			
Androgel pump	Testosterone TD Gel 20.25 MG/ACT (1.62%)	1.62 %	2	Bottles	30	DAYS			
Aveed	Testosterone Undecanoate IM Inj in Oil 750 MG/3ML (250MG/ML)	750 MG/3ML	1	Vial	28	DAYS			
Azmiro	testosterone cypionate im soln pref syringe in oil	200	4	Syringes	28	DAYS			
Depo-testosterone	Testosterone Cypionate IM Inj in Oil 100 MG/ML	100 MG/ML	1	Vial	28	DAYS			
Depo-testosterone	Testosterone Cypionate IM Inj in Oil 200 MG/ML	200 ; 200 MG/ML	10	Vials	28	DAYS			
Fortesta	Testosterone TD Gel 10MG/ACT (2%)	10 MG/ACT	2	Bottles	30	DAYS			
Jatenzo	Testosterone Undecanoate Cap 158 MG	158 MG	120	Capsules	30	DAYS			
Jatenzo	Testosterone Undecanoate Cap 198 MG	198 MG	120	Capsules	30	DAYS			
Jatenzo	Testosterone Undecanoate Cap 237 MG	237 MG	60	Capsules	30	DAYS			
Kyzatrex	Testosterone Undecanoate Cap	100 MG	60	Capsules	30	DAYS			
Kyzatrex	Testosterone Undecanoate Cap	150 MG	120	Capsules	30	DAYS			
Kyzatrex ; Undecatrex	Testosterone Undecanoate Cap	200 MG	120	Capsules	30	DAYS			
Methitest	Methyltestosterone Oral Tab 10 MG	10 MG	600	Tablets	30	DAYS			
Natesto	Testosterone Nasal Gel 5.5 MG/ACT	5.5 MG/ACT	3		30	DAYS			
Testim ; Vogelxo	Testosterone TD Gel 50 MG/5GM (1%)	1 % ; 50 MG/5GM	60	Containers	30	DAYS			
Testopel	Testosterone Implant Pellets 75 MG	75 MG	6	Pellets	90	DAYS			
Tlando	Testosterone Undecanoate Cap	112.5 MG	120	Capsules	30	DAYS			

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Vogelxo pump	Testosterone TD Gel 12.5 MG/ACT (1%)	1 %	4	Bottles	30	DAYS			
Xyosted	Testosterone Enanthate Solution Auto-Injector 100 MG/0.5ML	100 MG/0.5 ML	2	mLs	28	DAYS			
Xyosted	Testosterone Enanthate Solution Auto-Injector 50 MG/0.5ML	50 MG/0.5 ML	2	mLs	28	DAYS			
Xyosted	Testosterone Enanthate Solution Auto-Injector 75 MG/0.5ML	75 MG/0.5 ML	2	mLs	28	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Commercial ; HIM ; ResultsRx
			Commercial ; HIM ; ResultsRx
	danazol cap	100 MG ; 200 MG ; 50 MG	Commercial ; HIM ; ResultsRx
	methyltestosterone cap	10 MG	Commercial ; HIM ; ResultsRx
	oxandrolone tab	10 MG ; 2.5 MG	Commercial ; HIM ; ResultsRx
	testosterone enanthate im inj in oil	200 MG/ML	Commercial ; HIM ; ResultsRx
	testosterone td soln	30 MG/ACT	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
Azmiro	testosterone cypionate im soln pref syringe in oil	200	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 ; 200 MG/ML	Commercial ; HIM ; ResultsRx
Jatenzo ; Kyzatrex ; Tlando ; Undecatrex	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
Testopel	Testosterone Implant Pellets 75 MG	75 MG	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
			Commercial ; HIM ; ResultsRx
	Methyltestosterone Cap 10 MG	10 MG	Commercial ; HIM ; ResultsRx
	testosterone enanthate im inj in oil	200 MG/ML	Commercial ; HIM ; ResultsRx
	Testosterone TD Gel 20.25 MG/1.25GM (1.62%)	20.25 MG/1.25GM	Commercial ; HIM ; ResultsRx
	Testosterone TD Gel 40.5 MG/2.5GM (1.62%)	40.5 MG/2.5GM	Commercial ; HIM ; ResultsRx
	testosterone td soln	30 MG/ACT	Commercial ; HIM ; ResultsRx
Androderm	testosterone td patch	2 MG/24HR ; 4 MG/24HR	Commercial ; HIM ; ResultsRx
Androgel	Testosterone TD Gel 25 MG/2.5GM (1%)	25 MG/2.5GM	Commercial ; HIM ; ResultsRx
Androgel pump	Testosterone TD Gel 20.25 MG/ACT (1.62%)	1.62 %	Commercial ; HIM ; ResultsRx
Aveed	Testosterone Undecanoate IM Inj in Oil 750 MG/3ML (250MG/ML)	750 MG/3ML	Commercial ; HIM ; ResultsRx
Azmiro	testosterone cypionate im soln pref syringe in oil	200	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 ; 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 ; Undecatrex	Testosterone Undecanoate Cap	200 MG	Commercial ; HIM ; ResultsRx
Methitest	Methyltestosterone Oral Tab 10 MG	10 MG	Commercial ; HIM ; ResultsRx
Natesto	Testosterone Nasal Gel 5.5 MG/ACT	5.5 MG/ACT	Commercial ; HIM ; ResultsRx
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
Tlando	Testosterone Undecanoate Cap	112.5 MG	Commercial ; HIM ; ResultsRx
Vogelxo pump	Testosterone TD Gel 12.5 MG/ACT (1%)	1 %	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	**TARGET AGENT(S)** **Androderm** (testosterone patch) **Androgel*** (testosterone gel) **Aveed** (testosterone undecanoate injection solution) **Azmiro** (testosterone cypionate intramuscular injection solution) **danazol capsule*** **Depo-Testosterone*** (testosterone cypionate injection solution) **Fortesta*** (testosterone gel) **Jatenzo** (testosterone undecanoate capsule) **Kyzatrex** (testosterone undecanoate capsule) **Methitest** (methyltestosterone tablet) **methyltestosterone capsule*** **Natesto** (testosterone nasal gel) **Testim*** (testosterone gel) **Testopel** (testosterone pellet) **Testosterone Enanthate intramuscular injection solution** **testosterone topical solution*** **Tlando** (testosterone undecanoate capsule) **Undecatrex** (testosterone undecanoate capsule) **Vogelxo*** (testosterone gel) **Xyosted** (testosterone enanthate injection solution) * - generic available **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, Aveed, Fortesta, Jatenzo, Kyzatrex, Natesto, Testim, testosterone topical solution, Tlando, Undecatrex, Vogelxo, or Xyosted, the patient has a diagnosis of ONE of the following: 1. Primary or secondary (hypogonadotropic) hypogonadism **OR** 2. Gender dysphoria/gender incongruence **OR** B. If the request is for Azmiro, Depo-Testosterone, or 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 dysphoria/gender incongruence **OR** C. If the request is for testosterone enanthate intramuscular injection solution, 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. Breast cancer **OR** 4. Gender dysphoria/gender incongruence **OR** D. If the request is for danazol, the patient has a diagnosis of ONE of the following: 1. Endometriosis amenable to hormone management **OR** 2. Hereditary angioedema and will be taking for the prevention of attacks **OR** 3. Myelofibrosis associated anemia **OR** E. 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. 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:

Module	Clinical Criteria for Approval
	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 gender dysphoria/gender incongruence, then 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 comprehensive biopsychosocial assessment has been conducted by a qualified physician AND the prescriber has consulted with other medical professionals (e.g., mental health professional, endocrinologist) when required **AND** 2. The parents or other caretakers or guardians were involved in the assessment process, unless their involvement has been determined to be harmful to the adolescent or not feasible **AND** 3. A persistent diagnosis of gender dysphoria/gender incongruence has been marked and sustained over time **AND** 4. ONE of the following: A. The patient is 16 years of age or over **OR** B. There is support for initiating therapy prior to 16 years of age **AND** 5. The patient has been informed and counseled regarding effects and side effects of sex hormone treatment, including those which are irreversible, and the potential loss of fertility and options available to preserve fertility **AND** 6. The patient has sufficient emotional and cognitive maturity required to provide informed consent/assent for treatment **AND** 7. The patient has provided informed consent/assent for treatment AND, as applicable, the parents or other caretakers or guardians have provided consent to therapy **AND** 8. The patient's coexisting mental health concerns, physical conditions, or social problems that may interfere with diagnosing and/or sex hormone treatment have been addressed to provide optimal treatment **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 of gender dysphoria/gender incongruence has been marked and sustained over time **AND** 2. Other possible causes of apparent gender incongruence have been identified and excluded prior to initiation of treatment **AND** 3. The patient has been informed and counseled regarding effects and side effects of sex hormone treatment, including those which are irreversible, and the potential

Module	Clinical Criteria for Approval

loss of fertility and options available to preserve fertility **AND**

4. The patient has sufficient emotional and cognitive maturity required to provide informed consent for treatment **AND**
5. The patient has provided informed consent for treatment **AND**
6. The patient's coexisting mental health and/or physical conditions that could have a negative impact on sex hormone treatment have been addressed, with risks and benefits discussed, to provide optimal treatment **OR**

B. The patient is currently on sex hormone treatment and BOTH of the following:
   1. ONE of the following:
      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 for the patient's gender identity OR is less than 300 ng/dL **OR**
         2. Free serum testosterone level that is within OR below the testing laboratory's normal range for the patient's gender identity **OR**
      B. There is support for continuing therapy with the patient's current testosterone level **AND**
   2. The patient is being monitored at least once per year **OR**

C. If the request is for delayed puberty in an adolescent, then ONE of the following:
   1. The patient's sex is male **OR**
   2. There is support that the requested agent is medically appropriate for the patient's sex **OR**

D. If the request is for breast cancer, then ONE of the following:
   1. BOTH of the following:
      1. The patient is 1 to 5 years postmenopausal **AND**
      2. The patient has inoperable metastatic breast cancer **OR**
   2. ALL of the following:
      1. The patient is premenopausal **AND**
      2. The patient has benefitted from oophorectomy **AND**
      3. The patient has a hormone-responsive tumor **OR**

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

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

G. If the request is for myelofibrosis associated anemia, then ONE of the following:
   1. The patient has a serum erythropoietin (EPO) greater than or equal to 500 mU/mL **OR**
   2. The patient has a serum erythropoietin (EPO) less than 500 mU/mL and had no response or loss of response to an erythropoiesis-stimulating agent (ESA) **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
Aveed
Azmiro

Module	Clinical Criteria for Approval
	Fortesta, Testosterone gel Jatenzo Kyzatrex Methitest Natesto Testim Testopel Tlando Undecatrex Vogelxo, Testosterone gel Xyosted

   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 for the requested indication **OR**
   B. There is support for 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.

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 [Note: patients not previously approved for the requested agent will require initial evaluation review] **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**

Module	Clinical Criteria for Approval

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

B. The patient has a diagnosis of gender dysphoria/gender incongruence AND ONE of the following:
1. If the patient is an adult, then 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 for the patient's gender identity OR is less than 300 ng/dL **OR**
B. Free serum testosterone level that is within OR below the testing laboratory's normal range for the patient's gender identity **OR**
2. There is support for 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 or gender dysphoria/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
Aveed
Azmiro
Fortesta, Testosterone gel
Jatenzo
Kyzatrex
Methitest
Natesto
Testim
Testopel
Tlando
Undecatrex
Vogelxo, Testosterone gel
Xyosted

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: 1. The patient will NOT be using the requested agent in combination with another androgen or anabolic steroid agent for the requested indication **OR** 2. There is support for 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.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Universal QL	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months