CLINICAL MONOGRAPH · HORMONE OPTIMIZATION

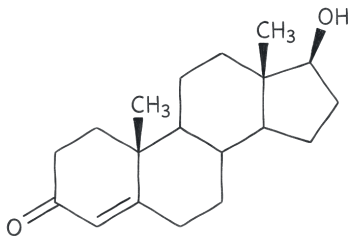
Testosterone

Bioidentical testosterone for hormone optimization

Testosterone is the body's main androgen hormone, the same molecule your testes (or, in women, ovaries and adrenal glands) make naturally. Doctors prescribe testosterone for men whose bodies no longer make enough (a condition called hypogonadism), and in carefully selected cases for post-menopausal women with low sexual desire.

There are many FDA-approved testosterone products: weekly or biweekly injections (cypionate, enanthate), longer-acting injections (Aveed), daily skin gels (AndroGel, Testim), nasal gel (Natesto), under-the-tongue or gum products (Striant), pellets implanted under the skin (Testopel), and a weekly self-injector (Xyosted) [rogol2016natesto; gittelman2019xyosted].

RonanRx can also compound bioidentical testosterone when a patient needs something the manufactured products don't offer, a specific ester, a custom strength, a troche, a scrotal cream, or a formulation without a particular excipient [wang2000gel]. Testosterone is a Schedule III controlled substance, so it requires a prescription, careful recordkeeping, and ongoing monitoring of blood counts, PSA, and clinical response [bhasin2018endo; snyder2016ttrials; fda503a].



EVIDENCE POSTURE FDA APPROVED WELL STUDIED REVIEWED **2026-05-11**

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State-licensed 503A | Pharmacist reviewed | Doctor led | Cold-chain ready | Patient choice preserved

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FOR CLINICIANS

Testosterone replacement therapy (TRT) is indicated for men with classical hypogonadism, consistent symptoms plus unequivocally low morning total testosterone confirmed on a repeat measurement, per the Endocrine Society 2018 clinical practice guideline (Bhasin) and the AUA 2018 guideline (Mulhall) [bhasin2018endo; mulhall2018aua]. Replacement aims to restore serum testosterone to the mid-normal range and to ameliorate hypogonadism-related symptoms. Numerous FDA-approved formulations exist across IM, subcutaneous, transdermal, buccal, intranasal, and pellet routes.

Pivotal evidence: the Testosterone Trials (T-Trials, Snyder 2016 NEJM and follow-on JAMA / JAMA Intern Med publications) demonstrated benefit for sexual function, mood, walking distance, anemia, and volumetric bone density in older men with unequivocally low testosterone, with mixed/null cognitive findings and a coronary plaque-volume signal in the Budoff substudy [snyder2016ttrials; budoff2017plaque]. TRAVERSE [lincoff2023traverse] was the FDA-mandated cardiovascular outcomes trial: non-inferior for MACE vs placebo in men with hypogonadism and elevated CV risk, while showing increased rates of atrial fibrillation, acute kidney injury, and pulmonary embolism in the treated arm. The earlier TOM trial [basaria2010tom] had been stopped early for an excess of cardiovascular events in frail older men receiving testosterone gel [coviello2008erythro].

Compounded testosterone occupies a legitimate, long-standing 503A niche, ester selection, custom strengths, troches, scrotal/transdermal creams, intranasal preparations, not a copy-of-approved-product framing. Schedule III controlled substance handling, baseline and on-therapy hematocrit (erythrocytosis risk; dose-dependent per Coviello 2008 and Ohlander 2018), PSA in age-appropriate men, fertility counseling (exogenous testosterone suppresses spermatogenesis; recovery covered by McBride 2016 and Ramasamy 2015), and individualized cardiovascular risk discussion are required [ohlander2018erythro; mcbride2016recovery; ramasamy2015fertility].

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Why Personalized Testosterone

The FDA-approved testosterone dose schedules (cypionate 50 to 400 mg IM every 2 to 4 weeks, gel 1.62 percent applied daily) were calibrated for trial populations with hypogonadism, not for the specific man in front of the prescriber. Trial averages do not adjust for a starting total testosterone of 180 versus 320 ng/dL, a 38-year-old versus a 62-year-old, baseline hematocrit drifting toward 52 percent, an estradiol that rises sharply on aromatization, or a partner trying to conceive. Those are the variables that decide whether a given regimen lands as physiologic replacement or as a rolling supraphysiologic peak.

That is the work a compounding pharmacy does. The molecule is the same one the FDA reviewed. What changes is the fit: a 100 mg/mL cypionate concentration dosed twice weekly subcutaneously instead of the 200 mg/mL bolus every two weeks, a propionate preparation for a patient who needs shorter ester half-life around fertility-preservation cycles, a transdermal cream at a non-commercial strength for a man who runs hot on injectables, or a co-prescribed anastrozole troche and HCG sterile vial so estradiol control and intratesticular signaling are handled in the same protocol rather than three separate manufactured products.

This is the older arrangement that pre-dates mass manufacturing: a prescriber who knows the labs, a pharmacist who prepares the medication for that named patient, a chain of custody on every lot. Modern oversight, the same molecule, fit to the person.

Quick Facts About Testosterone

Category: Endogenous androgen (anabolic steroid hormone); Schedule III controlled substance

Active ingredients: Testosterone (bioidentical); various esters, testosterone cypionate, testosterone enanthate, testosterone propionate, testosterone undecanoate

FDA-approved branded products: Numerous: AndroGel (transdermal gel), Testim (gel), Axiron (axillary solution), Fortesta/Vogelxo (gel), Striant (buccal), Testopel (subcutaneous pellets), Aveed (long-acting IM undecanoate), Natesto (intranasal), Xyosted (subcutaneous enanthate auto-injector), Depo-Testosterone (IM cypionate), Delatestryl (IM enanthate), Androderm (transdermal patch)

Routes studied in humans: Intramuscular (esters), subcutaneous (Xyosted, pellets, compounded cypionate), transdermal (gel, cream, patch), buccal, intranasal, oral undecanoate, troche (compounded)

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Evidence posture: FDA-approved manufactured products for male hypogonadism are well-studied; landmark trials include the T-Trials (Snyder 2016), TRAVERSE cardiovascular outcomes (Lincoff 2023), TOM (Basaria 2010), and Endocrine Society / AUA practice guidelines (Bhasin 2018; Mulhall 2018)

FDA-approval status: Multiple FDA-approved manufactured products for primary or hypogonadotropic hypogonadism in men. Compounded variants are not FDA-approved but address established patient-specific clinical needs not met by the manufactured market.

Compounded under: 503A, patient-specific prescription only; Schedule III controlled substance handling required

Compounded role: Distinct from 'essentially-a-copy' territory: patient-specific compounding addresses ester selection (cypionate vs enanthate vs propionate), custom strengths and concentrations, alternate dosage forms (troche, scrotal/transdermal cream, intranasal), excipient sensitivity, and dose individualization that the manufactured market does not offer.

Schedule: Schedule III controlled substance under the Controlled Substances Act; dispensing, recordkeeping, and refill limits per DEA

SPECIALS: PATIENT-SPECIFIC PRESCRIPTION ONLY

Testosterone described in this monograph is a 503A compounded preparation. Every dose is made on a prescription, for a named patient, by a licensed pharmacist. It is not a stocked, mass-manufactured product.

- **Made to order, not off a shelf.** No batch sits in a warehouse waiting for buyers. Your prescription triggers the prep.
- **Named-patient label.** The bottle carries one patient's name. The batch records carry one prescription.
- **Dose, strength, and route chosen for the patient.** A prescriber decides what gets compounded, not a manufacturer who set the strength for a trial population.
- **Licensed pharmacist on the hook.** A real person, with a license that can be pulled, signs off on every prep. State inspectors check the facility.
- **Compounded drugs are not FDA-approved.** They should not be evaluated using branded-drug trial data alone. Availability varies by state and prescribed medication.

How This Differs from a Research-Use-Only Website

A research-use-only website ships a vial from a warehouse. There is no prescription, no pharmacist, no facility inspection, and no way to recall the product if something is wrong with it. If the vial is mislabeled, contaminated, or under-potent, there is nobody whose license is at stake.

A 503A compounding pharmacy is the other thing. The doctor writes the prescription. A licensed pharmacist, whose name is on the label, prepares the medicine in a facility the state inspects. If something goes wrong, there is a person and a license on the hook, and a documented chain of custody on every lot. That accountability is what makes it safe.

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What is Testosterone?

Testosterone (17β-hydroxy-4-androsten-3-one) is the principal endogenous androgen in humans. In men, it is produced primarily by the Leydig cells of the testes under pulsatile pituitary luteinizing hormone (LH) stimulation; smaller amounts derive from adrenal androgen precursors. In women, testosterone is produced by the ovarian theca cells and by adrenal precursor conversion. Circulating testosterone is largely bound to sex hormone-binding globulin (SHBG) and albumin; free and weakly bound (bioavailable) testosterone drives most tissue effects.

Bioidentical testosterone, the same chemical entity as the endogenous hormone, has been available pharmaceutically since the 1930s, when it was synthesized and characterized concurrently by Butenandt and Ruzicka. Replacement therapy for hypogonadism has been in continuous clinical use since the 1950s [bhasin2018endo].

The molecule itself is delivered in many forms: testosterone esters (cypionate, enanthate, propionate, undecanoate) that release free testosterone slowly after IM or SC injection; transdermal gels, patches, and creams; buccal bioadhesive tablets; intranasal gels; subcutaneous pellets; and oral undecanoate (in some markets) [nieschlag2006age; wang2000gel]. Each formulation is a different solution to the same delivery challenge: avoiding first-pass hepatic metabolism while producing physiologic serum levels.

How Testosterone Works

Testosterone acts at the androgen receptor (AR), a nuclear hormone receptor expressed in muscle, bone, fat, prostate, brain, hair follicles, and many other tissues [heinlein2002coregulators]. Ligand binding triggers nuclear translocation and transcription of androgen-responsive genes [mooradian1987androgens]. In some tissues, testosterone is converted to dihydrotestosterone (DHT) by 5α-reductase, DHT is a more potent AR agonist and drives prostate and external genital effects [andersson1991reductase] [jenkins1992reductase]. In other tissues, testosterone is aromatized to estradiol by aromatase (CYP19A1), estradiol drives bone, lipid, and some sexual-function effects of testosterone in men [mauras2000estrogen].

Replacement therapy raises serum testosterone toward the mid-normal range, with downstream effects on muscle mass and strength, erythropoiesis, bone density, fat distribution, libido, erectile function, and mood [finkelstein2013gonadal]. The T-Trials [snyder2016ttrials] demonstrated benefit across these domains in older men with low testosterone, with effect sizes that varied by indication. Reference ranges have been harmonized across the major cohort studies [travison2017refrange].

Importantly, exogenous testosterone suppresses pituitary LH and FSH through hypothalamic-pituitary-gonadal feedback. This shuts down endogenous testicular testosterone production and spermatogenesis.

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The clinical consequence is that men on TRT have markedly reduced fertility while on therapy, often with full or partial recovery after cessation [mcbride2016recovery] [bhasin2018endo; ramasamy2015fertility].

Biological Role of Testosterone

Testosterone is the principal mediator of male sexual development and adult androgen-dependent physiology. During fetal life it drives Wolffian duct differentiation; at puberty it drives growth of the external genitalia, voice deepening, body hair, muscle and bone growth, and the establishment of adult sexual function. In adult men, testosterone maintains libido, erectile function, spermatogenesis (via intratesticular concentrations approximately 100-fold higher than serum), erythropoiesis, lean body mass, bone density, and mood [islam2019women].

In women, testosterone is a normal physiologic hormone, circulating concentrations approximately one-tenth of male levels, with established roles in sexual function, mood, and contributions to bone and muscle physiology. The Endocrine Society [wierman2014women], Global Consensus Position Statement [davis2019consensus], and Islam 2019 Lancet Diabetes & Endocrinology meta-analysis address testosterone's role in post-menopausal women with hypoactive sexual desire dysfunction (HSDD) [islam2019women].

Endogenous testosterone declines with age in men (approximately 1, 2% per year after age 30), with a subset of men developing symptomatic late-onset hypogonadism. The Endocrine Society defines clinical hypogonadism as the combination of consistent symptoms plus unequivocally low morning total testosterone confirmed on a repeat measurement [bhasin2018endo], rather than age-related decline alone [islam2019women].

Detailed Mechanism of Testosterone

Androgen receptor structure. The androgen receptor (AR) is a member of the nuclear receptor superfamily encoded on the X chromosome [heinlein2002coregulators]. Like other steroid receptors, it has a modular domain organization, an N-terminal transactivation domain, a central DNA-binding domain with two zinc-finger motifs that recognize androgen-response elements in target-gene promoters, a hinge region, and a C-terminal ligand-binding domain. Unliganded AR resides in the cytoplasm complexed with heat-shock proteins; ligand binding induces conformational change, displacement of chaperones, homodimerization, nuclear translocation, and recruitment of coactivator complexes that drive transcription of androgen-responsive genes [mooradian1987androgens]. Beyond this classical genomic pathway, AR also signals via rapid, nongenomic effects through plasma-membrane-associated complexes that engage kinase cascades (Heinlein 2002 nongenomic).

5α-reductase pathway. In androgen-target tissues including prostate, hair follicle, external genitalia, and skin, testosterone is converted to the more potent agonist dihydrotestosterone (DHT) by 5α-reductase. Two

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isoforms, type 1 (predominantly liver and skin) and type 2 (predominantly prostate and external genitalia), were cloned and pharmacologically characterized in the early 1990s by Andersson and Jenkins [jenkins1992reductase]. Loss-of-function mutations in 5α-reductase type 2 produce a recognizable disorder of sex development [andersson1991reductase]. DHT binds AR with greater affinity and slower dissociation than testosterone, amplifying androgen signaling in tissues that express the reductase.

Aromatization to estradiol. Aromatase (CYP19A1) converts testosterone to estradiol and androstenedione to estrone. In men, aromatization occurs in adipose tissue, bone, brain, and the Leydig cells themselves; the estradiol generated locally and systemically mediates a substantial fraction of testosterone's effect on bone density and lipid metabolism. Pharmacologic aromatase suppression in men reproduces specific features of estrogen deficiency despite preserved testosterone [mauras2000estrogen]. The Finkelstein 2013 NEJM goserelin-suppression study with separate testosterone and anastrozole add-back arms is the foundational dissection of which androgenic phenotypes are testosterone-mediated and which are estradiol-mediated [finkelstein2013gonadal].

Sex hormone-binding globulin (SHBG) physiology. Circulating testosterone exists in three pools, a tightly bound fraction (~40, 60%) on SHBG, a weakly bound fraction (~40, 60%) on albumin, and a free fraction (~1, 2%) [travison2017refrange]. The free hormone hypothesis [mendel1989free] holds that only unbound steroid is biologically available to enter cells by diffusion; bioavailable testosterone (free plus albumin-bound) is the operational summary clinicians use. SHBG concentration is regulated by hepatic estrogen exposure, thyroid status, insulin signaling, and inflammation; alterations in SHBG (obesity, hyperinsulinemia, hyperthyroidism, hypothyroidism, hepatic disease) drive much of the discrepancy between total and free testosterone clinicians encounter [bhasin2018endo].

Intracellular conversion at target tissues. The same circulating testosterone produces tissue-specific effects depending on the local complement of converting enzymes and coregulators. Prostate and skin express 5α-reductase type 2 and convert testosterone to DHT locally, explaining why finasteride and dutasteride attenuate prostate and scalp effects without lowering serum testosterone. Adipose tissue and brain express aromatase, local conversion to estradiol explains testosterone's bone, fat-mass, and some libido effects. Muscle expresses AR but not 5α-reductase at high levels, so muscle anabolism is driven by testosterone directly [travison2017refrange]. This tissue-selective intracrinology is the molecular basis for the distinct anabolic versus androgenic phenotypes of androgen action.

Anabolic versus androgenic mechanisms. The anabolic effects (skeletal muscle hypertrophy, lean mass, erythropoiesis, bone formation) are largely AR-mediated effects of testosterone itself in tissues with low 5α-reductase activity, and they are dose-dependent across the physiologic and supraphysiologic range [bhasin1996supra]. The androgenic effects (prostate growth, sebum production, hair-follicle response, virilization of external genitalia) require local DHT conversion. Erythropoiesis is partially direct (AR-mediated EPO induction in renal interstitial cells) and partially indirect (suppression of hepcidin and increased iron-restricted erythropoiesis; Bachman 2014) [bachman2014hepcidin].

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Post-receptor signaling cascades. Genomic AR signaling proceeds via DNA-bound AR-coactivator complexes (including SRC/p160 family, p300/CBP, and tissue-specific factors) that remodel chromatin at androgen-response-element-flanked target genes (Heinlein 2002 coregulators) [heinlein2002coregulators]. Nongenomic AR signaling activates phosphatidylinositol 3-kinase / Akt, MAP kinase, and Src-family kinase cascades on a faster timescale and is implicated in muscle hypertrophy and bone-cell survival (Heinlein 2002 nongenomic) [heinlein2002nongenomic]. The HPG feedback that underlies fertility suppression is a separate hypothalamic loop: GnRH pulsatility from arcuate / preoptic neurons drives LH and FSH; exogenous testosterone (and aromatized estradiol) suppress GnRH pulse amplitude/frequency, reducing LH/FSH and shutting down testicular testosterone synthesis and spermatogenesis [bhasin2001dose]. Brief pulsatile delivery (intranasal Natesto TID) incompletely suppresses LH and partially preserves spermatogenesis [rogol2016natesto].

Testosterone Research History

Testosterone was isolated and characterized in the 1930s by three independent groups (Butenandt, Ruzicka, and Laqueur), with Butenandt and Ruzicka sharing the 1939 Nobel Prize in Chemistry for sex-hormone work. Synthetic and esterified testosterone preparations (propionate, then enanthate and cypionate) entered clinical use through the 1940s and 1950s as injectable replacement therapy for primary hypogonadism [fernandez2010meta; pencina2023anemia] [roy2017anemia]. Foundational biology of androgen action was synthesized by Mooradian's 1987 Endocrine Reviews piece, and the molecular dissection of the androgen receptor and its 5α-reductase / aromatase co-pathways was completed across the 1990s and 2000s [andersson1991reductase] [mooradian1987androgens; heinlein2002coregulators; heinlein2002nongenomic].

Subcutaneous pellet implants (Testopel), among the oldest still-marketed delivery forms, were rigorously pharmacokinetically characterized by Handelsman in 1990 and refined by Kelleher in 2001 and 2004 [kelleher2001pellet; kelleher2004pellet]. The 1990s brought transdermal delivery. Testosterone scrotal patches preceded non-scrotal patches (Androderm), and then transdermal gels, AndroGel (FDA-approved 2000) and Testim, became dominant outpatient formulations [borst2015meta; davis2008nejm; kingsberg2007benefit]. Wang 2000 and Swerdloff 2000 characterized the pharmacokinetics of transdermal gel and established that controlled daily application produced physiologic levels with less peak-trough variability than esters [swerdloff2000pk; wang2004striant; snyder2017bone]. Buccal bioadhesive (Striant, Wang 2004; Korbonits 2004) and oral undecanoate (in some markets) followed [korbonits2004striant] [wang2000gel; resnick2017cognition].

Population-level characterization of late-onset hypogonadism advanced in the 2000s through the European Male Aging Study (EMAS): Wu and colleagues published the operational symptom-plus-laboratory definition of late-onset hypogonadism in NEJM 2010 [wu2010emas] and Tajar's 2012 follow-up characterized the heterogeneity of primary, secondary, and compensated forms [tajar2012emas] [pencina2024sexfn]. Travison and Bhasin's 2017 harmonization of total testosterone reference ranges

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across four major cohorts (CARDIA, EMAS, FHS, Osteoporotic Fractures in Men Study) provided the cross-cohort 264, 916 ng/dL reference range now widely cited [budoff2017plaque; travison2017refrange; bhasin2024prostate].

The 2010s expanded the route palette. Aveed (testosterone undecanoate IM, FDA-approved 2014) gave 10-week dosing intervals [minnemann2008undecanoate]. Natesto (intranasal gel, FDA-approved 2014) preserved spermatogenesis better than other formulations because brief intranasal pulses incompletely suppress LH [rogol2016natesto]. Xyosted (testosterone enanthate auto-injector for weekly SC dosing, FDA-approved 2018) addressed needle-anxiety and produced steadier serum levels than IM dosing [kaminetsky2019xyosted52] [saad2007undecanoate; gittelman2019xyosted]. Testopel pellets (3, 6 month duration) remain in use. Bachman and colleagues (2014) clarified that testosterone-induced erythropoiesis involves suppression of hepcidin and resetting of the EPO-hemoglobin set point, explaining the dose-dependent erythrocytosis quantified earlier by Coviello 2008 [bachman2014hepcidin; coviello2008erythro] [wierman2014women].

Cardiovascular safety dominated the 2010s clinical-evidence debate. Vigen 2013 (JAMA) reported observational excess mortality / MI / stroke in a Veterans Affairs cohort [vigen2013jama]. Xu 2013 (BMC Medicine), Fernández-Balsells 2010 (JCEM), Borst 2015 (Am J Physiol), and Alexander 2017 (Am J Med) meta-analyzed the pre-TRAVERSE randomized data with varying conclusions ranging from no excess risk to suggestion of harm with transdermal routes. The TOM trial [basaria2010tom] was stopped early for excess CV events in frail older men [cunningham2016sexfn]. The FDA-mandated cardiovascular outcomes trial TRAVERSE [lincoff2023traverse] finally provided definitive randomized data: non-inferior for MACE, with increased atrial fibrillation, AKI, and pulmonary embolism. The TRAVERSE substudy program [snyder2024fracture] extended the safety/benefit dataset across organ systems. Hudson's 2022 individual-participant-data meta-analysis (Lancet Healthy Longevity) integrated pre- and TRAVERSE-era trials [xu2013meta; alexander2017meta; hudson2022ipd].

Parallel: the Testosterone Trials [snyder2016ttrials] established efficacy across sexual function, mood, walking distance, anemia, and bone in men with classical hypogonadism [braunstein2005patch; islam2019women]. The T4DM trial [wittert2021t4dm] demonstrated reduction in incident type 2 diabetes when testosterone was added to lifestyle modification in overweight and obese men with prediabetes or screening-detected diabetes [bhasin2024diabetes] [davis2019consensus]. For women, Davis's 2008 NEJM trial of transdermal testosterone for postmenopausal HSDD, the earlier Braunstein 2005 and Kingsberg 2007 patch studies, the Wierman 2014 Endocrine Society women's guideline, and the Davis 2019 Global Consensus / Islam 2019 Lancet D&E meta-analysis comprise the women's evidence base [bhasin2018endo; jenkins1992reductase; handelsman1990pellet].

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Testosterone Timeline

1935 • Butenandt and Ruzicka independently synthesize testosterone from cholesterol; Laqueur isolates testosterone from bull testes

1939 • Butenandt and Ruzicka share Nobel Prize in Chemistry for sex-hormone work

1953 • Testosterone cypionate (Depo-Testosterone) introduced, long-ester depot injection becomes the workhorse of replacement therapy

1987 • Mooradian, Morley, and Korenman publish 'Biological actions of androgens' Endocrine Reviews, foundational synthesis of androgen-receptor physiology before the molecular era [mooradian1987androgens]

1989 • Mendel publishes 'The free hormone hypothesis' Endocrine Reviews, formalizes the conceptual basis for bioavailable vs total testosterone in target-tissue exposure [mendel1989free]

1990 • Handelsman publishes pharmacokinetics and pharmacodynamics of testosterone pellets in man, provides the PK basis for subcutaneous pellet replacement (Testopel) [handelsman1990pellet]

1991 • Andersson, Berman, Jenkins, and Russell publish Nature paper on 5α-reductase type 2 gene deletion in male pseudohermaphroditism, anchors the two-isoenzyme model of DHT biosynthesis [andersson1991reductase]

1992 • Jenkins, Andersson, Imperato-McGinley, Wilson, and Russell publish genetic and pharmacological evidence for more than one human steroid 5α-reductase (JCI), completes the type 1 / type 2 isozyme dissection [jenkins1992reductase]

1996 • Bhasin et al publish landmark study in NEJM showing supraphysiologic testosterone increases muscle size and strength in normal men with or without exercise [bhasin1996supra]

1999 • Behre et al publish phase I pharmacokinetics of intramuscular testosterone undecanoate in male hypogonadism [behre1999tu]

2000 • FDA approves AndroGel (transdermal testosterone gel); Wang and Swerdloff publish pivotal pharmacokinetic and clinical-outcomes papers [wang2000gel; swerdloff2000pk]

2000 • Mauras publishes 'Estrogen suppression in males: metabolic effects' (JCEM), demonstrates that aromatase inhibition in men reproduces specific features of estrogen deficiency despite preserved testosterone, foundational for the testosterone-vs-estradiol dissection in men [mauras2000estrogen]

2001 • Bhasin et al publish testosterone dose-response relationships in healthy young men, Am J Physiol Endocrinol Metab [bhasin2001dose]

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2001 • Kelleher publishes influence of implantation site and track geometry on the extrusion rate and pharmacology of testosterone implants (Clin Endocrinol), refines clinical handling of subcutaneous pellets [kelleher2001pellet]

2002 • Heinlein and Chang publish two foundational Endocrine Reviews papers, 'AR coregulators: an overview' and 'The roles of ARs and androgen-binding proteins in nongenomic androgen actions', establishing the modern molecular model of AR signaling [heinlein2002coregulators; heinlein2002nongenomic]

2003 • FDA approves Striant (buccal bioadhesive testosterone tablet)

2004 • Wang and Korbonits publish pharmacokinetic characterization of buccal testosterone (Striant) in hypogonadal men [wang2004striant; korbonits2004striant]

2004 • Kelleher publishes testosterone release rate and duration of action of testosterone pellet implants (Clin Endocrinol), quantitative basis for the 3, 6 month pellet interval [kelleher2004pellet]

2005 • Braunstein publishes RCT of transdermal testosterone patch in women with HSDD after oophorectomy (Arch Intern Med), early controlled trial of testosterone in postmenopausal HSDD [braunstein2005patch]

2005 • Calof et al publish meta-analysis of adverse events with testosterone replacement in middle-aged and older men [calof2005ae]

2007 • Kingsberg publishes clinically meaningful benefit analysis of the testosterone patch in postmenopausal women with HSDD (J Sex Med), informs effect-size interpretation for women's HSDD trials [kingsberg2007benefit]

2007 • Saad et al publish eight-year clinical experience with long-acting parenteral testosterone undecanoate [saad2007undecanoate]

2008 • Coviello et al publish graded-dose testosterone effects on erythropoiesis in young and older men, defines the dose-dependence of erythrocytosis risk [coviello2008erythro]

2008 • Minnemann et al publish comparison of long-acting testosterone undecanoate vs enanthate [minnemann2008undecanoate]

2008 • Davis et al publish NEJM RCT of transdermal testosterone for postmenopausal women with low libido not taking estrogen, best-known women's HSDD efficacy trial [davis2008nejm]

2010 • Wu et al publish 'Identification of late-onset hypogonadism in middle-aged and elderly men' (EMAS, NEJM), operational symptoms-plus-laboratory criteria for diagnosis [wu2010emas]

2010 • Fernández-Balsells et al publish JCEM systematic review and meta-analysis of adverse effects of testosterone therapy [fernandez2010meta]

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2010 • Basaria et al publish TOM trial (NEJM), stopped early for cardiovascular adverse events in frail older men receiving transdermal testosterone [basaria2010tom]

2012 • Tajar et al characterize primary, secondary, and compensated hypogonadism in aging men in the EMAS cohort (JCEM) [tajar2012emas]

2013 • Vigen et al publish JAMA observational analysis of testosterone therapy and CV events in a Veterans Affairs cohort [vigen2013jama]

2013 • Xu et al publish BMC Medicine meta-analysis of testosterone therapy and cardiovascular events [xu2013meta]

2013 • Finkelstein et al publish NEJM gonadal-steroid suppression study clarifying the relative contributions of testosterone vs estradiol to body composition, strength, and sexual function in men [finkelstein2013gonadal]

2014 • Bachman et al publish 'Testosterone induces erythrocytosis via increased erythropoietin and suppressed hepcidin' (J Gerontol), mechanistic basis of testosterone-induced erythropoiesis [bachman2014hepcidin]

2014 • FDA approves Aveed (long-acting testosterone undecanoate IM) and Natesto (intranasal testosterone gel)

2014 • Wierman et al publish updated Endocrine Society clinical practice guideline on androgen therapy in women [wierman2014women]

2014, 2015 • FDA issues safety communications requiring class-wide cardiovascular labeling changes and mandating the post-marketing TRAVERSE outcomes trial

2015 • Borst et al publish American Journal of Physiology meta-analysis suggesting injection testosterone is safer than transdermal administration for cardiovascular events [borst2015meta]

2016 • Snyder et al publish the Testosterone Trials primary results in NEJM, benefit in sexual function, walking distance, mood/depressive symptoms, and anemia in older men with classical hypogonadism [snyder2016ttrials]

2016 • Cunningham et al publish JCEM T-Trials sexual function paper, detailed psychosexual outcomes [cunningham2016sexfn]

2016 • Rogol et al publish Natesto pivotal pharmacokinetic / efficacy data [rogol2016natesto]

2017 • Travison, Bhasin, and colleagues publish harmonized reference ranges for circulating testosterone levels in men of four cohort studies (JCEM), establishes cross-cohort 264, 916 ng/dL range [travison2017refrange]

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2017 • T-Trials substudy publications: Roy et al (anemia, JAMA Intern Med), Budoff et al (coronary plaque, JAMA), Resnick et al (cognition, JAMA); Snyder et al publish bone density results in JAMA Internal Medicine [roy2017anemia; budoff2017plaque; resnick2017cognition; snyder2017bone]

2017 • Hembree and Endocrine Society colleagues publish updated guideline on endocrine treatment of gender-dysphoric/gender-incongruent persons (JCEM), defines testosterone dosing for masculinizing gender-affirming care [hembree2017transgender]

2017 • Alexander et al publish Am J Med meta-analysis of cardiovascular risks of exogenous testosterone use [alexander2017meta]

2018 • FDA approves Xyosted (subcutaneous testosterone enanthate weekly auto-injector)

2018 • Bhasin et al publish updated Endocrine Society Clinical Practice Guideline on testosterone therapy in men with hypogonadism [bhasin2018endo]

2018 • Mulhall et al publish the AUA Guideline on evaluation and management of testosterone deficiency [mulhall2018aua]

2018 • Ohlander et al publish review of erythrocytosis following testosterone therapy [ohlander2018erythro]

2018 • Snyder et al publish 'Lessons From the Testosterone Trials' (Endocrine Reviews) consolidating T-Trial findings [snyder2018lessons]

2018 • Traustadóttir et al publish 3-year extension showing testosterone supplementation attenuates age-related decline in aerobic capacity (JCEM) [traustadottir2018aerobic]

2019 • Davis et al publish Global Consensus Position Statement on testosterone therapy for women; Islam et al publish Lancet D&E meta-analysis [davis2019consensus; islam2019women]

2019 • Kaminetsky and Gittelman publish 52-week and 26-week Xyosted safety/efficacy studies [kaminetsky2019xyosted52; gittelman2019xyosted]

2021 • Wittert et al publish T4DM (Lancet Diabetes & Endocrinology), testosterone added to lifestyle modification reduced incidence of type 2 diabetes in overweight/obese men with prediabetes or screening-detected diabetes [wittert2021t4dm]

2022 • Hudson et al publish Lancet Healthy Longevity individual-participant-data meta-analysis on adverse cardiovascular events and mortality in men during testosterone treatment [hudson2022ipd]

2022 • Coleman and colleagues publish WPATH Standards of Care for the Health of Transgender and Gender Diverse People, Version 8, current best-practice framework for gender-affirming testosterone use [coleman2022wpath]

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2023 • Lincoff et al publish TRAVERSE cardiovascular outcomes trial in NEJM, non-inferior for MACE; increased atrial fibrillation, AKI, and pulmonary embolism in the testosterone arm [lincoff2023traverse]

2023 • Pencina et al publish TRAVERSE anemia substudy (JAMA Netw Open), testosterone corrects anemia in hypogonadal men over 12 months [pencina2023anemia]

2023 • Valderrábano et al publish testosterone replacement protocol in prostate cancer survivors (Andrology), supports cautious replacement in selected prostate-cancer-survivor populations [valderrabano2023prostate]

2024 • TRAVERSE substudies published: Snyder et al on fractures (NEJM, increased fracture rate in testosterone arm), Bhasin et al on diabetes progression (JAMA Intern Med, no effect on prediabetes-to-diabetes progression), Bhasin et al on prostate risk and monitoring (JCEM), and Pencina et al on sexual function and hypogonadal symptoms (JCEM) [snyder2024fracture; bhasin2024diabetes; bhasin2024prostate; pencina2024sexfn]

Clinical Contexts for Testosterone

Primary or hypogonadotropic hypogonadism in men FDA APPROVED

FDA-approved indication for multiple manufactured testosterone products.

Testosterone replacement is FDA-approved for adult men with classical primary (testicular failure) or hypogonadotropic (pituitary or hypothalamic) hypogonadism. Diagnosis per Endocrine Society 2018 guideline (Bhasin) and AUA 2018 guideline (Mulhall) requires consistent symptoms plus unequivocally low morning total testosterone confirmed on a repeat measurement [bhasin2018endo; mulhall2018aua]. Goal of therapy is to restore serum testosterone to the mid-normal range and ameliorate symptoms. The T-Trials [snyder2016ttrials] demonstrated benefit in sexual function, walking distance, mood, anemia, and bone density in older men with classical hypogonadism.

Branded product: AndroGel, Testim, Androderm, Striant, Testopel, Aveed, Natesto, Xyosted, Depo-Testosterone, Delatestryl, Axiron, Fortesta, Vogelxo

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Cardiovascular safety in middle-aged and older men with hypogonadism WELL STUDIED

Addressed by the FDA-mandated TRAVERSE cardiovascular outcomes trial.

TRAVERSE [lincoff2023traverse] found testosterone non-inferior to placebo for major adverse cardiovascular events over a mean 33-month follow-up. Treated men had higher rates of atrial fibrillation, acute kidney injury, and pulmonary embolism. The earlier TOM trial [basaria2010tom] had been stopped for an excess of cardiovascular events in frail older men on transdermal testosterone, and the Vigen 2013 JAMA observational analysis raised similar concern [vigen2013jama]. The Budoff 2017 T-Trials substudy reported greater coronary noncalcified plaque-volume progression in the testosterone arm than placebo, though without an MI signal in the parent T-Trials [budoff2017plaque].

Postmenopausal hypoactive sexual desire dysfunction (HSDD) WELL STUDIED

Off-label in the United States; supported by international guidelines and meta-analysis.

The 2019 Global Consensus Position Statement (Davis) and the Islam 2019 Lancet Diabetes & Endocrinology meta-analysis of 36 RCTs support short-term use of testosterone in physiologic doses for postmenopausal women with HSDD, with measurable improvement in sexual events, desire, arousal, and orgasm [davis2019consensus; islam2019women]. The Endocrine Society 2014 guideline (Wierman) endorsed a trial in selected postmenopausal women with HSDD [wierman2014women]. No FDA-approved testosterone product exists for women in the United States; compounded preparations or off-label use of low-dose male products are the practical options. Long-term safety data beyond 24 months remain limited.

Effects on body composition and physical function in older men WELL STUDIED

Well-studied in the T-Trials and Finkelstein gonadal-suppression studies.

Replacement to mid-normal range improves lean mass, strength, and walking distance in older men with classical hypogonadism (T-Trials, Snyder 2016 NEJM). Finkelstein 2013 NEJM established that testosterone drives lean-mass changes while estradiol (derived from testosterone via aromatization) drives fat-mass changes, providing the mechanistic basis for the role of aromatization in male androgen physiology [bhasin1996supra; bhasin2001dose]. Snyder 2017 (JAMA Intern Med) demonstrated increased volumetric bone density and strength on QCT in older men receiving testosterone for one year [snyder2016ttrials; snyder2017bone; finkelstein2013gonadal].

Anemia of hypogonadism / anemia of aging WELL STUDIED

Well-studied; demonstrated benefit in T-Trials anemia substudy.

Testosterone is a physiologic erythropoietic stimulus. The T-Trials anemia substudy and the Pencina 2023 hypogonadism anemia RCT demonstrated correction of anemia in hypogonadal men. The dose-response relationship of testosterone with hematocrit [coviello2008erythro] underlies both the therapeutic effect on anemia and the adverse-event risk of erythrocytosis [snyder2018lessons]. Ohlander 2018 reviewed monitoring and management of treatment-emergent erythrocytosis [ohlander2018erythro].

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Off-Label Uses of Testosterone

Postmenopausal HSDD in women

WELL STUDIED

Supported by international guidelines; no FDA-approved product for women in the US.

Use of low-dose testosterone (physiologic female-range serum levels) is supported by the 2019 Global Consensus Position Statement (Davis) and the Islam 2019 meta-analysis [davis2019consensus; islam2019women]. Compounded female-strength preparations or off-label fractional dosing of male products are used in practice [wierman2014women]. Monitor for androgenic adverse effects (acne, hirsutism, voice changes) and confirm serum levels remain in the female physiologic range.

Gender-affirming masculinizing therapy

WELL STUDIED

Used per WPATH and Endocrine Society transgender-care guidelines; not addressed in detail on this page.

Testosterone is the principal hormone of masculinizing gender-affirming therapy. Dosing, monitoring, and shared decision-making follow WPATH Standards of Care and the Endocrine Society guidelines on endocrine treatment of gender-incongruent persons [bhasin2018endo]. RonanRx compounded testosterone is dispensed in this context only on a patient-specific prescription from the patient's clinician; this page does not substitute for those guidelines.

Age-related decline without symptomatic hypogonadism

EMERGING

Not recommended by Endocrine Society or AUA guidelines.

Treating age-related testosterone decline in the absence of consistent symptoms plus unequivocally low confirmed morning total testosterone is not recommended by the Endocrine Society 2018 guideline (Bhasin) or the AUA 2018 guideline (Mulhall) [bhasin2018endo; mulhall2018aua]. Direct-to-consumer 'low-T' marketing has historically pushed therapy outside the guideline-supported population; RonanRx does not support that framing.

FDA-Approved Uses of Testosterone

Brand	Indication	Year	Route
AndroGel	Testosterone replacement for male hypogonadism	2000	Transdermal gel
Testim	Testosterone replacement for male hypogonadism	2002	Transdermal gel

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Brand	Indication	Year	Route
Androderm	Testosterone replacement for male hypogonadism	1995	Transdermal patch
Striant	Testosterone replacement for male hypogonadism	2003	Buccal bioadhesive tablet
Testopel	Testosterone replacement for male hypogonadism	1972	Subcutaneous pellet implant
Depo-Testosterone	Testosterone replacement for male hypogonadism	1979	Intramuscular (testosterone cypionate in oil)
Delatestryl	Testosterone replacement for male hypogonadism	1953	Intramuscular (testosterone enanthate in oil)
Aveed	Testosterone replacement for male hypogonadism	2014	Intramuscular (testosterone undecanoate)
Natesto	Testosterone replacement for male hypogonadism	2014	Intranasal gel
Xyosted	Testosterone replacement for male hypogonadism	2018	Subcutaneous auto-injector (testosterone enanthate)
Fortesta / Vogelxo	Testosterone replacement for male hypogonadism	2010	Transdermal gel
Axiron	Testosterone replacement for male hypogonadism	2010	Topical axillary solution
Jatenzo / Tlando	Testosterone replacement for male hypogonadism	2019	Oral (testosterone undecanoate)

Numerous FDA-approved testosterone products are available across IM, SC, transdermal, buccal, intranasal, oral undecanoate, and pellet routes [wang2000gel; wang2004striant]. All are indicated for testosterone replacement in adult men with primary (testicular failure) or hypogonadotropic (pituitary or hypothalamic) hypogonadism [minnemann2008undecanoate]. Diagnostic criteria per the Endocrine Society 2018 guideline (Bhasin) and AUA 2018 guideline (Mulhall) require consistent symptoms plus unequivocally low morning total testosterone confirmed on a repeat measurement [bhasin2018endo; mulhall2018aua].

No FDA-approved testosterone product exists for women in the United States [rogol2016natesto; kaminetsky2019xyosted52]. Postmenopausal HSDD use is supported by international guidelines [davis2019consensus] and meta-analysis [islam2019women] but is off-label in US practice.

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Compounded Testosterone (503A)

Compounded testosterone occupies a long-standing legitimate role under 503A that is meaningfully distinct from typical 'essentially-a-copy' compounding. The manufactured market is wide but not exhaustive: it offers cypionate and enanthate IM (commonly 200 mg/mL), undecanoate IM (Aveed, fixed-strength prefilled), a narrow band of gel concentrations, a single buccal product, a single intranasal product, and pellets at a fixed strength. Patient-specific compounding addresses needs the manufactured market does not, alternative esters (propionate for shorter-action profiles), custom strengths (subphysiologic doses for women's HSDD; intermediate strengths for titration), alternative dosage forms (troches, scrotal cream, transdermal cream at custom concentrations), and excipient-free or excipient-substituted preparations.

Per FDA guidance on compounded copies of approved drugs, the prescribing clinician documents the patient-specific clinical reason [fda_essentially_a_copy]. For testosterone the documented reasons are typically formulation/route the manufactured market does not provide (troche, scrotal cream, female-physiologic strength), ester preference based on past tolerability or PK characteristics, or excipient sensitivity. Routine substitution of a compounded cypionate vial for a manufactured cypionate vial without a documented clinical reason is not the appropriate framing.

Testosterone is a Schedule III controlled substance. Every compounded testosterone prescription is dispensed under DEA recordkeeping requirements for Schedule III drugs, with patient-specific prescription authorization, controlled-substance ordering, locked storage, and full chain-of-custody documentation [fda503a; bhasin2018endo].

Testosterone Formulations and Routes

Form	Concentration	Description
Testosterone cypionate injection (IM or SC)	100 mg/mL, 200 mg/mL (custom strengths available)	Long-ester depot in cottonseed oil (or alternative oil for compounded). Subcutaneous administration is now commonly used in addition to IM; smaller more frequent SC doses produce steadier serum levels than larger IM doses every 2 weeks.
Testosterone enanthate injection (IM or SC)	100 mg/mL, 200 mg/mL	Long-ester depot in sesame oil (or alternative). Pharmacokinetics similar to cypionate; SC weekly dosing studied formally in the Xyosted development program.
Testosterone propionate injection	100 mg/mL	Short-ester depot for IM or SC use; frequent injection interval (every 1, 3 days). Compounded use is uncommon outside specific clinical scenarios.

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Form	Concentration	Description
Testosterone transdermal cream (compounded)	1%, 2%, 10%, custom	Daily application to skin (scrotal or non-scrotal, per prescription). Used when the manufactured gel concentrations are not appropriate. Scrotal application gives higher absorption per mg than non-scrotal.
Testosterone troche (compounded)	Custom, typical 5, 50 mg per troche	Sublingual / buccal slow-dissolve troche. Bypasses first-pass metabolism; alternative to the manufactured buccal bioadhesive product for patients who tolerate troche but not the Striant adhesive matrix.
Testosterone intranasal gel (compounded variant)	Custom	Manufactured Natesto provides intranasal gel at a fixed concentration; compounded intranasal preparations may be dispensed for documented patient-specific need outside that product's range.
Testosterone undecanoate (oral or IM)	Oral: 40 mg/capsule (Jatenzo) or 200 mg/capsule (Tlando); IM: Aveed 750 mg/3 mL prefilled	Manufactured oral undecanoate is FDA-approved for hypogonadism; bypasses first-pass via lymphatic absorption. Aveed IM gives ~10-week dosing intervals.
Testosterone subcutaneous pellet (Testopel)	75 mg per pellet, implanted in subcutaneous fat	Manufactured pellets implanted in the subcutaneous tissue of the hip or buttock. Steady-state release over 3, 6 months.

Routes used in published literature: intramuscular, subcutaneous, transdermal, topical, buccal, intranasal, oral, sublingual, troche.

Testosterone Dosing

Route	Population	Range	Duration	Study type
Intramuscular or subcutaneous	Adult men with classical hypogonadism, testosterone cypionate or enanthate	Typical replacement: 50, 100 mg weekly SC or 100, 200 mg every 1, 2 weeks IM, titrated to mid-normal range trough total testosterone (approximately 400, 600 ng/dL on a level drawn before the next dose)	Indefinite while clinically beneficial and tolerated	Endocrine Society 2018 guideline; AUA 2018 guideline; mirrored by long-standing labeled regimens
	Adult men with hypogonadism,	Starting 75 mg SC weekly, titration to 50, 100 mg		Pivotal phase III safety and efficacy program

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Route	Population	Range	Duration	Study type
Subcutaneous (Xyosted)	manufactured weekly auto-injector	weekly based on serum total testosterone two weeks after the most recent dose	Indefinite while clinically beneficial	(Kaminetsky 2019; Gittelman 2019)
Intramuscular (long-acting undecanoate, Aveed)	Adult men with hypogonadism	750 mg IM on day 0, week 4, then every 10 weeks; deep gluteal injection administered under REMS observation due to risk of pulmonary oil microembolism / anaphylaxis	Indefinite while clinically beneficial	Manufactured FDA-approved regimen; Minnemann 2008; Saad 2007
Transdermal gel (manufactured products)	Adult men with hypogonadism	Daily application: AndroGel 1.62%, 20.25 to 81 mg testosterone per day (1 to 4 pump actuations); Testim 1%, 5 to 10 g gel daily (50, 100 mg testosterone); Fortesta 2%, 40, 70 mg per day; Axiron 2% solution, 60, 120 mg per day axillary	Indefinite while clinically beneficial	Wang 2000 pivotal pharmacokinetic and clinical-outcomes data; Swerdloff 2000 long-term PK
Buccal (Striant)	Adult men with hypogonadism	30 mg buccal tablet applied to gum twice daily (every 12 hours)	Indefinite while clinically beneficial	Wang 2004 and Korbonits 2004 pharmacokinetic data
Intranasal (Natesto)	Adult men with hypogonadism	11 mg per nostril three times daily (total 33 mg/day)	Indefinite while clinically beneficial	Rogol 2016 pivotal pharmacokinetic / efficacy data
Subcutaneous pellet (Testopel)	Adult men with hypogonadism	Typically 6, 12 pellets (450, 900 mg total) implanted every 3, 6 months	Indefinite while clinically beneficial	Long-standing labeled regimen; reviewed in Nieschlag 2006 and Endocrine Society 2018 guideline
Transdermal cream or troche (compounded)	Postmenopausal women, HSDD	Target physiologic female range: typically 0.5, 5 mg testosterone per day (cream or troche)	Trial of therapy 3, 6 months; reassess sexual function and androgenic	Global Consensus Position Statement (Davis 2019); Islam 2019 Lancet D&E meta-analysis; Endocrine

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Route	Population	Range	Duration	Study type
			adverse effects; long-term safety beyond 24 months not established	Society 2014 women's guideline (Wierman)

Doses listed reflect FDA-labeled regimens and published clinical-trial protocols, not RonanRx prescribing recommendations. The prescribing physician selects formulation, route, and starting dose based on the patient's clinical context (severity of hypogonadism, prior tolerability, fertility goals, formulation preference, prostate and CV risk profile, and shared decision-making) [bhasin2018endo].

Practical considerations across routes: IM cypionate/enanthate every 1, 2 weeks produces the largest peak-trough excursions; subcutaneous weekly dosing reduces those excursions and is now common practice [bhasin2018endo]. Long-acting undecanoate (Aveed) requires REMS-program observation. Transdermal gels require attention to inter-personal transfer (washing hands, covering treated skin around women and children). Natesto's three-times-daily regimen better preserves LH/FSH and spermatogenesis than other routes [rogol2016natesto], a fertility-relevant consideration. Pellets give the longest interval but require an in-office procedure.

Targeting mid-normal range (commonly serum total testosterone 400, 700 ng/dL on a trough draw for IM/SC routes; mid-morning for gels) is the standard end-point [mulhall2018aua]. Patient-reported symptom response, libido, energy, mood, erectile function, is weighted alongside the laboratory level.

Testosterone Safety

Testosterone safety has been characterized over decades of clinical use plus, more recently, large randomized trial programs. The most clinically important on-therapy adverse events are dose-dependent erythrocytosis (rise in hematocrit; Coviello 2008 established the dose-response, Ohlander 2018 reviewed management), suppression of spermatogenesis with reduced fertility while on therapy [30], modest fluid retention and acne, and, at supraphysiologic doses, gynecomastia from aromatization to estradiol [2531].

Cardiovascular safety is the area of largest historical controversy. TRAVERSE [8] is the FDA-mandated cardiovascular outcomes RCT and the highest-quality randomized data available: testosterone was non-inferior to placebo for MACE over a mean 33-month follow-up. Treated men had higher rates of atrial fibrillation, acute kidney injury, and pulmonary embolism. Older signals from TOM [9] and observational analyses [10] had raised concern; TRAVERSE addressed but did not eliminate cardiovascular risk discussion. The Budoff 2017 T-Trials substudy reported greater coronary noncalcified plaque-volume progression in the testosterone arm than placebo over 12 months in older men with low testosterone [5].

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Prostate safety: testosterone replacement is contraindicated in men with active prostate cancer or breast cancer. PSA monitoring at baseline and on therapy is standard per Endocrine Society and AUA guidelines [1]. The 'androgen-adequacy' framing [32] has largely replaced the older 'testosterone drives prostate cancer' narrative for men without active disease, though caution and urologic involvement remain appropriate in men with PSA elevation or prior prostate cancer history [2426].

Other considerations include sleep apnea exacerbation in susceptible men, mood and behavior effects, and, with supraphysiologic dosing, hepatotoxicity (primarily a concern with 17-α-alkylated oral anabolic steroids, not bioidentical testosterone esters; Aveed carries a specific warning for pulmonary oil microembolism / anaphylaxis at the time of injection) [2].

Contraindications

Testosterone replacement is contraindicated in: active prostate cancer or breast cancer in men; pregnancy (testosterone is a teratogen, virilization of a female fetus); known hypersensitivity to testosterone or formulation excipients; uncorrected severe erythrocytosis (hematocrit above the threshold defined by the prescribing clinician, commonly >54%); severe untreated obstructive sleep apnea; severe uncompensated heart failure; and in men actively trying to achieve fertility unless an alternative regimen (HCG, clomiphene, or selective estrogen receptor modulator strategy) is selected instead [25].

Relative contraindications and cautions per the Endocrine Society 2018 guideline (Bhasin) and AUA 2018 guideline (Mulhall) include unevaluated prostate nodule or PSA elevation, prior thromboembolic disease, and prior major adverse cardiovascular event within recent months [12]. Aveed has a REMS-required observation period after each injection due to pulmonary oil microembolism / anaphylaxis risk.

Drug interactions

Testosterone is metabolized hepatically; clinically relevant drug-drug interactions are limited compared with many other pharmacotherapies. Concomitant warfarin may require closer INR monitoring (testosterone can potentiate anticoagulant effect). Insulin and oral hypoglycemics may need dose adjustment in men whose glycemic control improves on replacement. Concomitant corticosteroids increase the risk of fluid retention. Aromatase inhibitors (anastrozole, letrozole) reduce conversion of testosterone to estradiol and may be co-prescribed in selected scenarios; concomitant 5α-reductase inhibitors (finasteride, dutasteride) reduce DHT conversion [1].

Transdermal product-specific consideration: inter-personal transfer of gel to women or children produces virilization risk. Patients are counseled to wash hands after application and to cover the treated area until absorbed.

Adverse events

Across the T-Trials and TRAVERSE program, on-therapy adverse events most commonly attributable to testosterone include: erythrocytosis (dose-dependent; Coviello 2008 quantified the dose-response,

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Ohlander 2018 reviewed monitoring and management), acne and oily skin, fluid retention, breast tenderness or mild gynecomastia, and, in some men, sleep-apnea exacerbation [24][25]. Reduced fertility from suppression of LH/FSH and spermatogenesis is consistent across formulations except partially for intranasal Natesto [21].

In TRAVERSE [8], the testosterone arm had higher rates of atrial fibrillation, acute kidney injury, and pulmonary embolism than placebo, with non-inferiority for MACE. The TOM trial [9] was stopped early for excess cardiovascular adverse events in frail older men. Calof 2005 meta-analyzed adverse events across earlier randomized trials of replacement in middle-aged and older men and identified elevated rates of erythrocytosis and PSA increase but not consistently elevated rates of prostate cancer detection [26].

Site-specific adverse events: IM injection, local pain, occasional sterile abscess; SC injection (Xyosted, compounded SC cypionate/enanthate), local irritation; gels, skin irritation, transfer risk; buccal, gum irritation, dysgeusia; intranasal, rhinorrhea, epistaxis; pellets, extrusion, infection at implant site; Aveed, REMS-monitored risk of pulmonary oil microembolism and anaphylaxis [23].

Monitoring Testosterone Therapy

Baseline assessment (per Endocrine Society 2018 / AUA 2018): morning total testosterone confirmed on a repeat measurement; SHBG with calculated or measured free testosterone where SHBG is suspected to be altered; LH and FSH (to differentiate primary vs secondary hypogonadism); complete blood count (baseline hematocrit); PSA and digital rectal exam in age-appropriate men (typically ≥40 years) with prostate-cancer risk discussion; lipid panel and HbA1c; fertility-goal counseling; symptom inventory [bhasin2018endo].

On-therapy monitoring: serum total testosterone 3, 6 months after initiation and after any dose change, with subsequent annual reassessment if stable [mulhall2018aua]. Timing of the draw depends on formulation, trough (just before next dose) for IM/SC esters; 2, 8 hours after application for gels; mid-cycle for pellets. Hematocrit at baseline, 3, 6 months, 12 months, and annually thereafter; dose reduction or temporary hold if hematocrit exceeds the threshold defined by the prescribing clinician (commonly 54%) per Ohlander 2018 [ohlander2018erythro].

PSA at 3, 12 months after initiation and annually thereafter in age-appropriate men. Symptom reassessment at each visit. Patients should report new-onset chest pain, dyspnea, leg swelling, or stroke-like symptoms promptly, particularly in light of the TRAVERSE atrial-fibrillation and PE signals [lincoff2023traverse].

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Testosterone in Special Populations

Testosterone Evidence Quality

Evidence for testosterone replacement in classical male hypogonadism is among the strongest in endocrinology [tajar2012emas; pencina2024sexfn] [pencina2023anemia]. Multiple FDA-approved manufactured products span IM, SC, transdermal, buccal, intranasal, and pellet routes, each supported by pivotal pharmacokinetic and clinical-outcomes programs [wang2000gel]. The Endocrine Society 2018 (Bhasin) and AUA 2018 (Mulhall) guidelines, together with the EMAS-derived diagnostic operationalization [wu2010emas] and Travison 2017 harmonized reference ranges, provide the consensus diagnostic and therapeutic framing [travison2017refrange; bhasin2024prostate].

The Testosterone Trials [snyder2016ttrials] are the highest-quality multi-domain randomized program in older men with classical hypogonadism [snyder2018lessons; cunningham2016sexfn]. TRAVERSE [lincoff2023traverse] is the FDA-mandated cardiovascular outcomes RCT and the definitive randomized cardiovascular-safety data set in men with hypogonadism plus elevated CV risk; its substudy program [snyder2024fracture] extends the safety/benefit dataset across organ systems [bhasin2024diabetes]. T4DM [wittert2021t4dm] is the largest randomized examination of testosterone in metabolic prevention [roy2017anemia; xu2013meta].

Pre-TRAVERSE cardiovascular safety was characterized by competing meta-analyses with heterogeneous conclusions: Calof 2005 (no consistent prostate-cancer excess), Fernández-Balsells 2010 (broad AE inventory), Xu 2013 (suggestion of CV risk), Borst 2015 (route-dependent CV risk with transdermal disadvantage), and Alexander 2017 (no consistent excess across pre-2017 RCTs) [fernandez2010meta] [alexander2017meta; braunstein2005patch]. Hudson 2022 (Lancet Healthy Longevity) integrated individual-patient data including TRAVERSE-era trials [hudson2022ipd].

For women, evidence is more limited and route-specific. Davis 2008 (NEJM) was the largest single RCT of transdermal testosterone for postmenopausal HSDD; earlier supporting RCTs include Braunstein 2005 and Kingsberg 2007 on the testosterone patch [borst2015meta; davis2008nejm; kingsberg2007benefit]. The Global Consensus Position Statement [davis2019consensus] and Islam 2019 Lancet D&E meta-analysis (8480 women, 36 RCTs) support short-term physiologic-dose testosterone for postmenopausal HSDD; long-term safety beyond 24 months is not established [calof2005ae; islam2019women]. No FDA-approved testosterone product exists for women in the United States [handelsman1990pellet; kelleher2001pellet; kelleher2004pellet]. For gender-affirming care, the Endocrine Society 2017 guideline (Hembree) and WPATH Standards of Care Version 8 [coleman2022wpath] define current best practice [bhasin2018endo; mulhall2018aua; hembree2017transgender].

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Evidence specifically supporting compounded preparations is observational and indirect; compounding is justified by patient-specific clinical need for formulations, strengths, or routes that the manufactured market does not offer [bhasin2018endo].

Major Testosterone Clinical Studies

Study	Design	Participants	Duration	Finding
TRAVERSE, Cardiovascular Safety of Testosterone-Replacement Therapy (Lincoff 2023 NEJM)	Phase IV randomized double-blind placebo-controlled FDA-mandated cardiovascular outcomes trial	5246	Mean 33 months	Testosterone non-inferior to placebo for major adverse cardiovascular events; increased atrial fibrillation, acute kidney injury, and pulmonary embolism in the testosterone arm [lincoff2023traverse]
The Testosterone Trials, Effects of Testosterone Treatment in Older Men (Snyder 2016 NEJM)	Coordinated set of seven double-blind placebo-controlled trials in older men with classical hypogonadism	790	12 months	Improvement in sexual function, walking distance, mood and depressive symptoms, and anemia; smaller effects in vitality and cognition [snyder2016ttrials]
T-Trials Bone Substudy (Snyder 2017 JAMA Internal Medicine)	Substudy of T-Trials, QCT bone density and strength	211	12 months	Increased volumetric bone density and estimated bone strength in spine and hip on testosterone vs placebo [snyder2017bone]
T-Trials Coronary Plaque Substudy (Budoff 2017 JAMA)	Substudy of T-Trials, coronary CT angiography	170	12 months	Greater progression of coronary noncalcified plaque volume on testosterone than placebo; no MACE imbalance in the parent T-Trials [budoff2017plaque]
T-Trials Cognition Substudy (Resnick 2017 JAMA)	Substudy of T-Trials, cognitive testing in men with age-associated memory impairment	493	12 months	No significant effect on delayed paragraph recall or other primary cognitive endpoints [resnick2017cognition]
Lessons From the Testosterone Trials (Snyder 2018	Narrative synthesis of the T-Trials program	—	Synthesis	Consolidated benefit/risk picture across sexual function, mood, vitality, bone, anemia, plaque, and

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Study	Design	Participants	Duration	Finding
Endocrine Reviews)				cognition substudies [snyder2018lessons]
TOM, Adverse Events Associated With Testosterone Administration (Basaria 2010 NEJM)	Randomized double-blind placebo-controlled trial of transdermal testosterone gel in older men with mobility limitations	209	Stopped early after 6 months	Trial stopped for excess cardiovascular adverse events in the testosterone arm in frail older men [basaria2010tom]
Gonadal Steroids and Body Composition (Finkelstein 2013 NEJM)	Goserelin-induced gonadal suppression with add-back testosterone ± anastrozole in healthy men	400	16 weeks	Testosterone primarily drives lean-mass changes; estradiol (derived from aromatization) primarily drives fat-mass changes, established the relative contribution of T vs E2 to male physiology [finkelstein2013gonadal]
Testosterone Dose-Response in Healthy Young Men (Bhasin 2001)	Randomized open-label dose-response study with gonadal suppression and graded testosterone enanthate add-back	61	20 weeks	Linear dose-response of fat-free mass, leg strength, and hemoglobin with testosterone dose; established the dose-effect curve carried into clinical replacement and supraphysiologic ranges [bhasin2001dose]
Supraphysiologic Testosterone in Normal Men (Bhasin 1996 NEJM)	Randomized placebo-controlled trial of testosterone enanthate 600 mg/week ± exercise in normal men	43	10 weeks	Supraphysiologic testosterone increased fat-free mass, muscle size, and strength even without exercise, defined the upper end of androgenic anabolic dose-response in humans [bhasin1996supra]
Effects of Graded Doses of Testosterone on Erythropoiesis (Coviello 2008 JCEM)	Gonadal-suppression dose-response in young and older men	61	20 weeks	Dose-dependent rise in hemoglobin and hematocrit; older men had greater erythropoietic response per dose than young men, provides the mechanistic basis for the erythrocytosis warning at higher replacement doses [coviello2008erythro]

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Study	Design	Participants	Duration	Finding
Erythrocytosis Following Testosterone Therapy (Ohlander 2018)	Narrative review	—	Review	Reviewed prevalence, mechanism, and management; provided the 50, 54% hematocrit threshold framework now used in clinical guidelines [ohlander2018erythro]
Vigen, Testosterone Therapy and Mortality / MI / Stroke (Vigen 2013 JAMA)	Retrospective observational cohort in a Veterans Affairs population	8709	Mean 27 months	Observational signal of increased CV events on testosterone; methodology debated; superseded as primary CV-risk evidence by TRAVERSE [vigen2013jama]
Calof, Adverse Events Meta-Analysis (Calof 2005)	Meta-analysis of randomized placebo-controlled trials of testosterone replacement in middle-aged and older men	19 trials, ~650 patients	Up to 3 years	Elevated rates of erythrocytosis and PSA increase on testosterone vs placebo; no consistent excess of detected prostate cancer [calof2005ae]
Endocrine Society Clinical Practice Guideline, Testosterone in Men with Hypogonadism (Bhasin 2018)	Clinical practice guideline	—	Synthesis	Diagnostic, therapeutic, and monitoring recommendations for testosterone replacement in adult men [bhasin2018endo]
AUA Guideline, Evaluation and Management of Testosterone Deficiency (Mulhall 2018)	Clinical practice guideline	—	Synthesis	Urology-focused recommendations on diagnosis, therapy, and monitoring [mulhall2018aua]
Transdermal Testosterone Gel, Pivotal RCT (Wang 2000 JCEM)	Randomized open-label clinical trial of AndroGel in hypogonadal men	—	180 days	Daily transdermal gel produced physiologic testosterone levels and improved sexual function, mood, muscle strength, and body composition [wang2000gel]
Long-Term Transdermal	Open-label long-term PK study	—	Up to 6 months	Stable serum testosterone over months of daily transdermal gel

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Study	Design	Participants	Duration	Finding
Testosterone Gel Pharmacokinetics (Swerdloff 2000 JCEM)				application; route established as a long-term option [swerdloff2000pk]
Natesto Intranasal Gel, Pivotal Study (Rogol 2016 Andrology)	Phase III open-label trial in hypogonadal men	—	90 days	TID intranasal gel normalized testosterone; better preservation of LH/FSH and spermatogenesis than other formulations [rogol2016natesto]
Xyosted Subcutaneous Testosterone Enanthate (Kaminetsky 2019; Gittelman 2019)	Phase III safety and efficacy programs	—	26 and 52 weeks	Weekly SC auto-injection produced steady serum testosterone with acceptable safety profile; basis for FDA approval (2018) [kaminetsky2019xyosted52; gittelman2019xyosted]
Striant Buccal Testosterone (Wang 2004 and Korbonits 2004 JCEM)	Pharmacokinetic comparison studies	—	Weeks	Twice-daily buccal bioadhesive tablet produced physiologic testosterone levels comparable to transdermal patch [wang2004striant; korbonits2004striant]
Testosterone Undecanoate IM, Phase I and Long-Term (Behre 1999; Minnemann 2008; Saad 2007)	Phase I pharmacokinetics and long-term registry/comparison studies	—	Weeks to years	Long-acting undecanoate IM gives stable testosterone with ~10-week injection intervals; basis for Aveed (US) and Nebido (ex-US) [behre1999tu; minnemann2008undecanoate; saad2007undecanoate]
Testosterone for Women, Global Consensus and Meta-Analysis (Davis 2019; Islam 2019)	Position statement and meta-analysis of 36 RCTs	8480 women (Islam)	12 weeks to 2 years	Short-term physiologic-dose testosterone improves sexual events, desire, arousal, orgasm, and pleasure in postmenopausal women with HSDD; long-term safety beyond 24 months not established [davis2019consensus; islam2019women]
Recovery of Spermatogenesis	Reviews and clinical series	—		Spermatogenesis suppression is consistent during exogenous

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Study	Design	Participants	Duration	Finding
after Testosterone or AAS (McBride 2016; Ramasamy 2015)			Months to years post-cessation	testosterone; recovery occurs in most men after cessation, with variable timing [mcbride2016recovery; ramasamy2015fertility]
T4DM, Testosterone for Type 2 Diabetes Prevention (Wittert 2021 Lancet D&E)	Randomized double-blind placebo-controlled phase 3b trial of testosterone undecanoate plus lifestyle in overweight/obese men with prediabetes or screening-detected diabetes	1007	2 years	Testosterone reduced incidence of type 2 diabetes vs lifestyle alone; weight loss and glycemic improvement larger with testosterone [wittert2021t4dm]
TRAVERSE Fracture Substudy (Snyder 2024 NEJM)	Pre-specified substudy of TRAVERSE	5204	Mean 3.2 years	Higher rate of clinical fractures in the testosterone arm than placebo, counterintuitive given prior T-Trials bone-density gain; emphasizes the difference between BMD and clinical fracture endpoints [snyder2024fracture]
TRAVERSE Diabetes Substudy (Bhasin 2024 JAMA Intern Med)	Pre-specified substudy of TRAVERSE in men with prediabetes	—	Through TRAVERSE follow-up	Testosterone did not reduce progression from prediabetes to type 2 diabetes in this elevated-CV-risk hypogonadal population, contrasts with the T4DM trial's positive effect in a different risk profile [bhasin2024diabetes]
TRAVERSE Prostate Risk Substudy (Bhasin 2024 JCEM)	Pre-specified substudy of TRAVERSE	—	Through TRAVERSE follow-up	Detailed analysis of prostate-cancer incidence, PSA trajectories, and prostate safety on testosterone vs placebo in hypogonadal men [bhasin2024prostate]
TRAVERSE Anemia Substudy (Pencina 2023 JAMA Netw Open)	Pre-specified substudy of TRAVERSE	—	12 months	Testosterone replacement corrected anemia in hypogonadal men with elevated CV risk; effect size consistent with prior T-Trials

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Study	Design	Participants	Duration	Finding
				anemia substudy [roy2017anemia] [pencina2023anemia]
TRAVERSE Sexual Function Substudy (Pencina 2024 JCEM)	Pre-specified substudy of TRAVERSE	—	Through TRAVERSE follow-up	Testosterone improved sexual activity, hypogonadal symptoms, and energy in men with hypogonadism and elevated CV risk, extends Cunningham 2016 T-Trials findings to a higher-CV-risk population [pencina2024sexfn]
T-Trials Sexual Function Substudy (Cunningham 2016 JCEM)	T-Trials sexual function substudy	470	12 months	Testosterone improved sexual activity, sexual desire, and erectile function vs placebo in older hypogonadal men; effect sizes modest but statistically robust [cunningham2016sexfn]
T-Trials Anemia Substudy (Roy 2017 JAMA Intern Med)	T-Trials anemia substudy	788	12 months	Testosterone corrected unexplained anemia in older men with low testosterone, both anemia of presumed inflammation and unexplained anemia improved on therapy [roy2017anemia]
Hudson Individual-Participant-Data Meta-Analysis (Hudson 2022 Lancet Healthy Longevity)	IPD and aggregate-data meta-analysis of randomized trials of testosterone in adult men	35 trials, 17,158 participants	Up to several years per trial	Testosterone treatment was not associated with significant increase in cardiovascular events or all-cause mortality in pooled randomized data, anticipated TRAVERSE result [hudson2022ipd]
Wu EMAS, Late-Onset Hypogonadism (Wu 2010 NEJM)	Prospective observational cohort, European Male Aging Study	3369	Cross-sectional plus longitudinal follow-up	Defined the operational symptoms-plus-laboratory criteria for late-onset hypogonadism, three sexual symptoms (low libido, ED, infrequent morning erections) plus total testosterone <11 nmol/L plus free testosterone <220 pmol/L [wu2010emas]
Tajar EMAS, Heterogeneity of		3369	Cross-sectional	Characterized primary, secondary (hypogonadotropic), and

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Study	Design	Participants	Duration	Finding
Hypogonadism (Tajar 2012 JCEM)	EMAS prospective cohort characterization		plus longitudinal	compensated hypogonadism phenotypes, clarified that secondary hypogonadism predominates in obese aging men, primary in lean aging men [tajar2012emas]
Travison Harmonized Reference Ranges (Travison 2017 JCEM)	Harmonization of total testosterone assays across four cohort studies (CARDIA, EMAS, FHS, Osteoporotic Fractures in Men)	Over 9000 men pooled	Cross-cohort	Harmonized total testosterone reference range 264, 916 ng/dL (9.2, 31.8 nmol/L) in healthy young men, widely adopted lower-bound cutoff for clinical hypogonadism [travison2017refrange]
Davis Transdermal Testosterone for Postmenopausal Women (Davis 2008 NEJM)	Phase III randomized double-blind placebo-controlled trial of transdermal testosterone in postmenopausal women with HSDD not taking estrogen	814	52 weeks	Testosterone 300 µg/day increased the frequency of satisfying sexual events and improved desire and arousal vs placebo; androgenic adverse effects modest and reversible [davis2008nejm]
Braunstein Testosterone Patch in Surgical Menopause (Braunstein 2005 Arch Intern Med)	RCT of transdermal testosterone in surgically menopausal women with HSDD on stable estrogen	447	24 weeks	Testosterone 300 µg/day increased frequency of total satisfying sexual activity and reduced personal distress vs placebo, early supporting evidence in surgical-menopause population [braunstein2005patch]
Kingsberg Clinical Relevance of Testosterone Patch Benefits (Kingsberg 2007 J Sex Med)	Pooled analysis of clinical meaningfulness across testosterone patch HSDD trials	—	Pooled trial data	Defined responder thresholds and clinically meaningful changes for testosterone HSDD trials in women, informs effect-size interpretation [kingsberg2007benefit]
Fernández-Balsells Adverse-Effects Meta-Analysis (Fernández-	Systematic review and meta-analysis of randomized testosterone trials	51 studies	Pooled	Inventoried adverse-event categories, confirmed PSA increase and erythrocytosis signals; insufficient power to confirm or

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Study	Design	Participants	Duration	Finding
Balsells 2010 JCEM)				exclude cardiovascular harm [fernandez2010meta]
Xu Cardiovascular Meta-Analysis (Xu 2013 BMC Medicine)	Meta-analysis of randomized testosterone trials with CV outcomes	27 trials, 2994 men	Pooled	Suggested elevated cardiovascular risk on testosterone vs placebo; methodologically debated, superseded by individual-participant-data and dedicated outcomes trials [xu2013meta]
Borst Injection vs Transdermal Cardiovascular Safety (Borst 2015 Am J Physiol)	Meta-analysis stratifying by route of administration	—	Pooled randomized data	Suggested IM injection produced less cardiovascular event excess than transdermal administration, informed pre-TRAVERSE prescribing debate [borst2015meta]
Alexander Cardiovascular Meta-Analysis (Alexander 2017 Am J Med)	Updated systematic review of cardiovascular events on exogenous testosterone	39 trials	Pooled	No statistically significant excess of MACE on testosterone vs placebo in pooled pre-TRAVERSE randomized data, informed FDA mandate for the dedicated TRAVERSE outcomes trial [alexander2017meta]
Bachman Testosterone and Hepcidin (Bachman 2014 J Gerontol)	Mechanistic study of testosterone's erythropoietic effect	—	Months	Testosterone increases erythropoietin and suppresses hepcidin, raising the EPO-hemoglobin set point, mechanistic basis of clinical erythrocytosis [bachman2014hepcidin]
Handelsman Pellet Pharmacokinetics (Handelsman 1990 JCEM)	Open-label PK and PD study of subcutaneous testosterone pellets in hypogonadal men	—	Up to 6 months per pellet cycle	Established the PK basis for the 3, 6 month pellet interval; serum testosterone profile with 200, 800 mg pellet doses [handelsman1990pellet]
Kelleher Pellet Release and Site Geometry (Kelleher 2001 Clin Endocrinol;	Clinical PK and explanation analyses of testosterone pellet implants	—	Months	Quantified pellet release rate, duration of action, and effect of implantation-site geometry on extrusion, practical basis for current pellet implantation

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Study	Design	Participants	Duration	Finding
Kelleher 2004 Clin Endocrinol)				technique [kelleher2001pellet; kelleher2004pellet]
Traustadóttir Long-Term Testosterone and Aerobic Capacity (Traustadóttir 2018 JCEM)	3-year randomized extension of testosterone supplementation in older men	—	36 months	Long-term testosterone supplementation attenuated age-related decline in VO2 peak vs placebo, extended-duration efficacy beyond the typical 1-year T-Trials window [traustadottir2018aerobic]
Valderrábano Testosterone in Prostate Cancer Survivors (Valderrábano 2023 Andrology)	Prospective clinical protocol in prostate-cancer survivors with testosterone deficiency	—	Months	Demonstrated cautious replacement protocols can be implemented in selected prostate-cancer survivor populations without consistent biochemical recurrence excess, emerging area of practice [valderrabano2023prostate]
WPATH Standards of Care Version 8 (Coleman 2022)	International multidisciplinary consensus guideline	—	Synthesis	Defines current best-practice framework for testosterone use in masculinizing gender-affirming care; cross-references Endocrine Society 2017 guideline (Hembree) [coleman2022wpath; hembree2017transgender]

Testosterone Pharmacokinetics & Pharmacodynamics

Pharmacokinetics

Bioidentical testosterone has very low oral bioavailability due to extensive first-pass hepatic metabolism, this is why effectively every clinically useful preparation either esterifies the molecule for IM/SC depot delivery, bypasses first-pass via transdermal, buccal, intranasal, or sublingual routes, or uses the undecanoate ester with lymphatic absorption (oral Jatenzo/Tlando) [saad2007undecanoate].

Injectable esters: cypionate and enanthate have similar pharmacokinetics, peak at approximately 24, 48 hours after IM injection, with serum testosterone returning toward the lower end of normal by 7, 10 days [minnemann2008undecanoate; kaminetsky2019xyosted52]. Twice-weekly or weekly SC dosing reduces peak-trough variability. Propionate has a much shorter ester half-life requiring every-1, 3-day dosing. Undecanoate IM (Aveed) gives a long flat profile over approximately 10 weeks [behre1999tu].

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Transdermal gels reach near-steady-state within 2, 3 days of daily application, with mid-application serum testosterone in the mid-normal range and modest day-to-day variability [wang2000gel] [swerdloff2000pk]. Buccal Striant produces serum levels within 30 minutes of application and sustained physiologic levels with twice-daily dosing [wang2004striant] [korbonits2004striant]. Intranasal Natesto produces brief serum pulses with each TID dose, a profile that preserves LH/FSH and spermatogenesis better than other formulations [rogol2016natesto]. Pellets (Testopel) release over 3, 6 months.

Pharmacodynamics

Pharmacodynamic effects are dose-dependent [bhasin1996supra]. Replacement to mid-normal range raises lean body mass, strength, hemoglobin, and bone mineral density, while reducing fat mass; effects on libido and erectile function depend on bringing serum testosterone above an individual threshold. Estradiol (derived by aromatization) is the principal mediator of testosterone's effects on fat mass and on some bone and sexual-function endpoints [finkelstein2013gonadal] [bhasin2001dose].

Hematologic pharmacodynamics: testosterone increases erythropoiesis directly via the androgen receptor and indirectly via suppression of hepcidin. The dose-response is steeper in older than younger men [coviello2008erythro], which underlies the erythrocytosis-risk warning. HPG-axis pharmacodynamics: exogenous testosterone suppresses LH and FSH, with downstream suppression of intratesticular testosterone and spermatogenesis [bhasin2001dose]. The exception is brief-pulse intranasal Natesto, which incompletely suppresses LH and partially preserves spermatogenesis [rogol2016natesto].

↓↑ Comparing Testosterone Formulations

Choice of formulation balances pharmacokinetic preference, fertility goals, patient comfort, and the manufactured-product range. IM/SC esters (cypionate, enanthate) are the historical workhorses, flexible, inexpensive, but with peak-trough variability that some patients feel. Long-acting undecanoate IM (Aveed) gives 10-week intervals but requires REMS-monitored injection. Transdermal gels avoid injections but require attention to transfer and produce smaller peak-trough swings [wang2000gel]. Buccal Striant [wang2004striant] is twice-daily without injections [korbonits2004striant]. Intranasal Natesto [rogol2016natesto] is the most fertility-sparing FDA-approved route. Xyosted [kaminetsky2019xyosted52] is a weekly self-administered SC auto-injection. Pellets (Testopel) give 3, 6 month duration but require an office procedure.

Compounded preparations expand the route palette: scrotal cream (higher absorption per mg than non-scrotal), troche (sublingual/buccal alternative to manufactured Striant), custom-concentration transdermal cream, and female-physiologic-strength preparations for HSDD [swerdloff2000pk; korbonits2004striant]. Compounded SC cypionate or enanthate is widely prescribed for men who prefer weekly SC dosing at non-Xyosted strengths or in oils other than the manufactured product's vehicle [gittelman2019xyosted; fda_essentially_a_copy].

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RonanRx compounds these preparations on patient-specific prescription, with documented clinical reason for compounding [swerdloff2000pk]. The pharmacist review confirms the prescribed formulation is responsive to a documented patient-specific need and is not routine substitution for a manufactured product.

Testosterone Storage and Handling

Compounded injectable testosterone preparations in oil are stored at controlled room temperature (USP definition 20, 25°C, with allowed excursions 15, 30°C) protected from light. Refrigeration is generally not required for ester-in-oil preparations and may cause crystallization of higher-concentration cypionate or enanthate solutions. Beyond-use dating follows USP <797> for sterile compounded preparations.

Transdermal creams, troches, intranasal preparations, and other non-sterile compounded forms are stored per the dispensing label, typically at controlled room temperature, with beyond-use dating per USP <795> non-sterile compounding standards [usp_797; usp_795]. Light-resistant packaging is preferred for testosterone-containing preparations.

Testosterone Compounding & Operations

503A compounding

RonanRx compounds testosterone preparations under 503A on patient-specific prescriptions. Sterile injectable preparations (compounded SC/IM cypionate, enanthate, propionate) follow USP General Chapter <797> for sterile pharmaceutical compounding, with documented active-ingredient sourcing (USP/NF grade), sterility and endotoxin testing per applicable risk-level requirements, gravimetric/volumetric verification, and full lot traceability [usp_795; usp_797]. Non-sterile preparations (troches, transdermal creams, oral capsules, intranasal vehicles) follow USP General Chapter <795>.

Testosterone is a Schedule III controlled substance under the Controlled Substances Act. RonanRx maintains DEA-registered controlled-substance handling: locked storage, biennial inventory, dispensing records retained per state and federal requirements, and limits on refills and transfer per Schedule III rules [fda503a]. Each prescription is verified for prescriber DEA registration and patient identity before dispensing.

Pharmacist review

Each prescription for compounded testosterone undergoes pharmacist review prior to dispensing. The review confirms: a documented patient-specific clinical reason for the compounded preparation (formulation/route not in the manufactured market, ester preference, custom strength, excipient sensitivity); diagnostic basis consistent with the Endocrine Society 2018 (Bhasin) and AUA 2018 (Mulhall)

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guideline framework; absence of contraindications (active prostate or breast cancer, pregnancy, uncorrected severe erythrocytosis); confirmation of baseline monitoring (testosterone level, hematocrit, PSA in age-appropriate men); appropriate Schedule III prescription elements [bhasin2018endo; mulhall2018aua].

RonanRx does not fill prescriptions for compounded testosterone that read as routine substitution for an available manufactured product without documented clinical rationale, consistent with FDA guidance on compounded copies of approved drugs [fda_essentially_a_copy].

Quality and traceability

Testosterone API is sourced from FDA-registered facilities with documented certificates of analysis. Each batch is recorded with lot numbers traceable to API source, compounding date, beyond-use date, and dispensing pharmacist of record. Sterile preparations carry sterility and endotoxin test documentation per USP <797> risk-level requirements [usp_797]. Schedule III controlled-substance ordering, receipt, and dispensing records are retained per DEA and state board of pharmacy requirements.

Cold chain

Most compounded testosterone preparations are not cold-chain products. Injectable ester-in-oil preparations and transdermal creams are shipped at controlled room temperature. Patients are instructed to store at room temperature in tightly closed containers, protected from light, and to contact the pharmacy if shipping temperature integrity is in doubt.

Frequently Asked Questions About Testosterone

Is compounded testosterone the same as AndroGel or Depo-Testosterone?

No. AndroGel, Depo-Testosterone, Xyosted, Aveed, Natesto, Striant, Testopel, and other branded testosterone products are FDA-approved manufactured products. Compounded preparations are pharmacy-prepared on a patient-specific prescription and are not FDA-approved [fda_essentially_a_copy]. They are dispensed when a documented patient-specific clinical need is not met by a manufactured product, for example, a specific ester, a custom strength, a troche, a scrotal cream, or an excipient-substituted preparation [fda503a].

When does compounded testosterone make clinical sense?

Common documented reasons include: a route the manufactured market does not provide (compounded transdermal cream at a non-manufactured concentration, troche, scrotal cream); a strength the manufactured market does not provide (female-physiologic doses for HSDD; intermediate doses for titration); an ester preference (propionate, custom-concentration cypionate or enanthate); or excipient

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sensitivity. Routine substitution of compounded for manufactured product without a documented reason is not appropriate [fda_essentially_a_copy; bhasin2018endo].

Will testosterone affect my fertility?

Yes. Exogenous testosterone suppresses pituitary LH and FSH, which shuts down endogenous testicular testosterone production and spermatogenesis. Men on TRT have markedly reduced fertility while on therapy. Recovery is typical after cessation but timing varies (McBride 2016; Ramasamy 2015) [mcbride2016recovery]. The intranasal Natesto formulation partially preserves spermatogenesis because of its brief-pulse pharmacokinetics (Rogol 2016) [rogol2016natesto]. Men with fertility goals should discuss alternatives (HCG, clomiphene, SERMs) with their prescriber before starting TRT [ramasamy2015fertility].

What does TRAVERSE tell us about cardiovascular risk?

TRAVERSE (Lincoff 2023 NEJM, n=5246) was the FDA-mandated cardiovascular outcomes trial in men with hypogonadism plus elevated CV risk [lincoff2023traverse]. Testosterone was non-inferior to placebo for major adverse cardiovascular events over a mean 33-month follow-up [basaria2010tom]. The treated arm had higher rates of atrial fibrillation, acute kidney injury, and pulmonary embolism. TRAVERSE clarified but did not eliminate cardiovascular-risk discussion; older signals from TOM (Basaria 2010) in frail men and observational data (Vigen 2013) remain part of shared decision-making [vigen2013jama].

What about prostate cancer risk?

Testosterone replacement is contraindicated in men with active prostate cancer or breast cancer. In men without active prostate cancer, the contemporary evidence (Calof 2005 meta-analysis; T-Trials; Morgentaler 2019 review) does not support a consistent excess of detected prostate cancer with replacement therapy, though PSA may rise modestly [calof2005ae; morgentaler2019prostate]. PSA monitoring at baseline and on therapy in age-appropriate men is standard [bhasin2018endo].

Can women take testosterone?

Yes, testosterone is a normal physiologic hormone in women, and post-menopausal HSDD is the best-supported off-label indication. The Global Consensus Position Statement (Davis 2019), Islam 2019 Lancet D&E meta-analysis, and Endocrine Society 2014 women's guideline (Wierman) support short-term physiologic-dose use [davis2019consensus; islam2019women; wierman2014women]. No FDA-approved testosterone product exists for women in the United States; compounded female-strength preparations or off-label fractional dosing of male products are used in practice. Long-term safety beyond 24 months is not established.

Why does my hematocrit need to be checked?

Testosterone is a physiologic erythropoietic stimulus and produces a dose-dependent rise in hematocrit (Coviello 2008) [coviello2008erythro]. At higher hematocrits (commonly above 54%) the prescribing

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clinician will reduce dose, lengthen the dosing interval, or temporarily hold therapy per the framework reviewed by Ohlander 2018 [ohlander2018erythro].

Does RonanRx sell testosterone directly to patients?

No. Testosterone is a Schedule III controlled substance dispensed only on a patient-specific prescription written by a licensed prescriber for an identified patient, with pharmacist review before dispensing. RonanRx is not a direct-to-consumer storefront [fda503a].

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How to Access Testosterone

Compounded Testosterone is dispensed under 503A on a patient-specific prescription. Depending on your role, the next step looks different.

FOR PRESCRIBING CLINICIANS

Offer this medication

A pharmacist will follow up within two business days. We'll cover state availability, supported formulations, and what integration looks like for your clinic.

ronanrx.com/request-partnership-call

PATIENT WITH A DOCTOR

Receive your prescription

If your doctor has prescribed Testosterone, sign up so we can prepare and ship your medication. The signup wizard collects intake and connects you to the prescribing workflow.

ronanrx.com/patients

PATIENT WITHOUT A DOCTOR

Find a partner clinic

RonanRx prescribes through partner clinics — we don't initiate prescriptions on this site. Read how the referral process works and how to find a partner clinic in your state.

ronanrx.com/find-clinic

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Other compounds RonanRx makes

This monograph is one of many in the RonanRx formulary. Every compound below is prepared under 503A on a patient-specific prescription. Browse the full catalog at ronanrx.com/medications and ronanrx.com/peptides, or scan the codes at right for each index.

Medications

Peptides

MEDICATIONS (40)

Alpha-Lipoic Acid (ALA) — Antioxidant & mitochondrial
Coenzyme Q10 (CoQ10) — Antioxidant & mitochondrial
Glutathione — Antioxidant & mitochondrial
NAD+ / NMN — Antioxidant & mitochondrial
Compounded Topical Anesthetics (BLT, LET) — Dermatology
Topical Minoxidil — Dermatology
Topical Tretinoin — Dermatology
Compounded Magnesium — Energy & nutritional
Cyanocobalamin — Energy & nutritional
High-Dose Vitamin D — Energy & nutritional
Hydroxocobalamin — Energy & nutritional
Iron (Compounded) — Energy & nutritional
L-Carnitine — Energy & nutritional
Methylcobalamin (B12) — Energy & nutritional
Methylfolate — Energy & nutritional
Anastrozole — Hormone optimization
Clomiphene & Enclomiphene — Hormone optimization
DHEA — Hormone optimization
Estradiol — Hormone optimization
Estriol — Hormone optimization
Human Chorionic Gonadotropin (HCG) — Hormone optimization
Pregnenolone — Hormone optimization
Progesterone — Hormone optimization
Testosterone — Hormone optimization
Compounded Metformin — Metabolic & weight
Compounded Semaglutide — Metabolic & weight
Compounded Tirzepatide — Metabolic & weight
Lipotropic Injection (MIC, MICC) — Metabolic & weight
Low-Dose Naltrexone (LDN) — Metabolic & weight
Naltrexone-Bupropion Combination — Metabolic & weight
Topiramate — Metabolic & weight
Bremelanotide / PT-141 — Sexual health
Compounded Sildenafil — Sexual health
Compounded Tadalafil — Sexual health
Trimix Injection — Sexual health
Compounded Gabapentin — Sleep & recovery
Compounded Melatonin — Sleep & recovery
Compounded T3 (Liothyronine) — Thyroid
Compounded T3/T4 Combinations — Thyroid
Compounded T4 (Levothyroxine) — Thyroid

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PEPTIDES (21)

Sermorelin — Available now

Tesamorelin — Available now

AOD-9604 — Growth-hormone axis (under FDA review)

CJC-1295 — Growth-hormone axis (under FDA review)

GHRP-2 / GHRP-6 — Growth-hormone axis (under FDA review)

Hexarelin — Growth-hormone axis (under FDA review)

Ipamorelin — Growth-hormone axis (under FDA review)

MK-677 / Ibutamoren — Growth-hormone axis (under FDA review)

5-Amino 1MQ — Metabolic & longevity (under FDA review)

Epitalon / Epithalon — Metabolic & longevity (under FDA review)

MOTS-C — Metabolic & longevity (under FDA review)

Thymosin Alpha-1 / Thymalin — Metabolic & longevity (under FDA review)

DSIP, Delta Sleep-Inducing Peptide — Neuro & cognitive (under FDA review)

Selank — Neuro & cognitive (under FDA review)

Semax — Neuro & cognitive (under FDA review)

Vasoactive Intestinal Peptide (VIP) — Neuro & cognitive (under FDA review)

BPC-157 — Tissue repair (under FDA review)

KPV — Tissue repair (under FDA review)

LL-37 — Tissue repair (under FDA review)

Pentadeca Arginate (PDA) — Tissue repair (under FDA review)

TB-500 / Thymosin Beta-4 — Tissue repair (under FDA review)

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