Informed Consent for Initiation of Masculinizing Gender-Affirming Hormone Therapy

Testosterone therapy for adult transmasculine / female-to-male / gender-diverse patients

Practice: _____
Clinician: _____
Date: _____
Patient legal name: _____
Name used: _____
DOB: _____
NHI: _____
Pronouns: _____
Interpreter used: ☐ No ☐ Yes: _____

1. Purpose of this consent

I am requesting treatment with **testosterone** as part of masculinizing gender-affirming hormone therapy.

I understand that informed consent is an ongoing process, not only a signature. I have had the opportunity to discuss the expected benefits, limitations, risks, alternatives, unknowns, monitoring requirements, fertility implications, contraception issues, and my personal medical risk factors with my clinician.

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2. Capacity, voluntariness, and eligibility

Please initial each statement:

Patient initials	Statement
_____	I am requesting masculinizing hormone therapy voluntarily.
_____	I understand the information given to me and have had time to ask questions.
_____	I understand that I may choose to delay, decline, or stop treatment.
_____	I understand that stopping testosterone should ideally be discussed with my clinician, especially if I have had ovaries removed.
_____	I understand that mental health concerns, if present, should be supported and managed, but do not automatically prevent treatment unless they impair my ability to give informed consent or safely participate in care.
_____	I understand that a genital examination is **not required** solely to start testosterone unless clinically indicated or requested by me.

3. Proposed treatment plan

Planned testosterone preparation

☐ Testosterone cypionate
☐ Testosterone enanthate
☐ Testosterone undecanoate
☐ Testosterone gel
☐ Testosterone patch
☐ Other: _____

Route

☐ Subcutaneous injection
☐ Intramuscular injection
☐ Transdermal gel
☐ Transdermal patch
☐ Other: _____

Starting dose: _____
Planned titration: _____
Target: Physiologic adult male testosterone range unless otherwise agreed.
Individualized goals: _____

I understand that higher-than-physiologic testosterone levels do **not** reliably produce faster or better masculinization and may increase adverse effects.

4. Alternatives discussed

Alternative	Discussed
No hormone therapy at this time	☐
Delaying treatment	☐
Lower-dose or slower testosterone titration	☐
Menstrual suppression without testosterone	☐
Fertility preservation before treatment	☐
Contraception options	☐
Voice therapy	☐
Hair removal or hair restoration options	☐
Chest binding / prosthetics / packing	☐
Gender-affirming surgery at a later stage	☐
Mental health, peer, or social support	☐

5. Expected masculinizing effects

I understand that testosterone affects each person differently. Genetics, age, dose, route, adherence, baseline hormones, and individual biology affect results. Changes may take months to years.

Change	Usual timing	Reversibility
Increased skin oiliness / acne	1-6 months	Usually partly reversible
Increased libido	1-6 months	Usually reversible
Vaginal/genital dryness or atrophy	1-6 months	Often treatable, partly reversible
Cessation of menses	1-6 months	Usually reversible if testosterone stopped, but variable
Clitoral / erectile genital tissue growth	1-6 months; max 1-2 years	Often irreversible or partly irreversible
Voice deepening	6-12 months; max 1-2 years	Usually irreversible
Facial and body hair growth	6-12 months; max 4-5 years	Often partly irreversible
Increased muscle mass / strength	6-12 months; max 2-5 years	Partly reversible
Fat redistribution	1-6 months; max 2-5 years	Partly reversible
Scalp hair thinning / male-pattern baldness	Variable	May be irreversible

6. Permanent or potentially irreversible changes

Please initial each item:

Patient initials	I understand this may be permanent or partly irreversible
_____	Deepening of the voice
_____	Facial and body hair growth
_____	Clitoral / erectile genital tissue enlargement
_____	Male-pattern scalp hair loss or balding
_____	Possible long-term effects on fertility

7. Fertility, pregnancy, and contraception

Patient Initial	Statement
_____	I understand testosterone may reduce fertility, but it does **not** guarantee infertility.
_____	I understand that stopping periods does **not** prove that ovulation has stopped.
_____	I understand testosterone is **not contraception**.
_____	I understand pregnancy can occur if I have a uterus/ovaries and have sex involving sperm exposure.
_____	I understand testosterone may harm a fetus and should not be used during pregnancy or when actively trying to conceive unless specifically directed by a specialist.
_____	Fertility preservation options, including oocyte or embryo cryopreservation, have been discussed.
_____	I have been offered referral to fertility services before starting testosterone.

Fertility decision

☐ I request fertility referral before starting testosterone.
☐ I decline fertility referral at this time.
☐ I have already completed fertility preservation.
☐ Fertility preservation is not relevant to my goals.
☐ Other: _____

Pregnancy risk assessment

Pregnancy possible? ☐ No ☐ Yes ☐ Unsure
Pregnancy test done today if indicated? ☐ No ☐ Yes: result _____
Contraception plan if pregnancy is possible and undesired:

8. Medical risks and complications

I understand that the following risks have been discussed.

Risk / complication	Explanation
Polycythemia / erythrocytosis	Testosterone can raise hemoglobin/hematocrit. Very high levels may increase risk of thrombosis, stroke, heart attack, headache, flushing, or other complications.
Cardiovascular risk	Blood pressure, lipids, weight, sleep apnea, smoking, diabetes, and family history affect risk. Long-term cardiovascular outcome data in transmasculine patients remain incomplete.
Hypertension	Blood pressure may rise or become harder to control.
Lipid changes	Cholesterol profile may worsen.
Weight and fluid changes	Weight, appetite, muscle mass, salt/water retention, or edema may change.
Diabetes / insulin resistance	Blood sugar control may worsen in some patients, especially with pre-existing diabetes or metabolic syndrome.
Obstructive sleep apnea	Testosterone may worsen snoring, sleep apnea, daytime sleepiness, morning headaches, or erythrocytosis.
Acne	Acne may occur or worsen, especially in the first year or with high testosterone peaks.
Androgenic alopecia	Scalp hair thinning or male-pattern baldness may occur, especially with genetic susceptibility.
Mood and mental health changes	Mood, irritability, anxiety, depression, libido, or energy may change. Cyclic symptoms can occur with injection peaks and troughs. Mania or psychosis risk should be considered in susceptible patients.
Migraine / headache	Migraines may improve or worsen; fluctuating hormone levels can be relevant.
Pelvic pain or cramping	May relate to uterine/ovarian activity, atrophy, endometriosis, pelvic floor dysfunction, infection, or pregnancy/ectopic pregnancy.
Persistent bleeding	Bleeding after several months of adequate testosterone needs review for dose, adherence, pregnancy, infection, and uterine/cervical pathology.

Risk / complication	Explanation
Vaginal/genital atrophy	Dryness, irritation, pain with sex, urinary symptoms, or recurrent infections may occur. Local treatments can be discussed.
Liver abnormalities	Standard injectable or transdermal testosterone is not usually strongly hepatotoxic, but liver monitoring may be needed in selected patients. Illicit or oral anabolic steroids can be dangerous.
Injection complications	Pain, bleeding, bruising, infection, scarring, incorrect dosing, or needle injury can occur.
Gel transfer	Testosterone gel can transfer to others by skin contact or contaminated clothing/bedding. Application instructions must be followed carefully.
Testosterone undecanoate -specific risk	Some long-acting injectable preparations carry rare risks such as pulmonary oil microembolism or anaphylaxis and may require monitored administration.
Cancer and organ-based screening	Retained cervix, uterus, ovaries, breast/chest tissue, or other organs still require appropriate screening and evaluation of symptoms.
Bone health	Stopping testosterone after oophorectomy, poor adherence, or prolonged low sex-steroid exposure may increase bone loss risk.
Unknown long-term effects	Some long-term outcomes remain incompletely known.

9. Conditions that may require specialist review, treatment delay, or modified dosing

Please tick any that apply:

☐ Current pregnancy
☐ Trying to conceive
☐ Active sex-hormone-sensitive cancer
☐ Prior breast, ovarian, uterine, cervical, or other hormone-sensitive cancer
☐ High hematocrit / polycythemia
☐ Uncontrolled hypertension
☐ Severe or untreated obstructive sleep apnea
☐ Recent heart attack, stroke, clot, or unstable cardiovascular disease
☐ Severe liver disease
☐ Uncontrolled diabetes
☐ Severe active psychiatric symptoms impairing consent or safety
☐ Current use of non-prescribed hormones or anabolic steroids
☐ Smoking/vaping nicotine
☐ Migraine with concerning neurologic features
☐ Other: _____

Clinical plan for identified risks:

10. Medication safety commitments

Please initial each statement:

Patient Initials	Statement
_____	I will take testosterone only as prescribed.
_____	I will not share, sell, or give testosterone to anyone else.
_____	I understand testosterone may be a controlled medication depending on jurisdiction.
_____	I will not increase the dose without discussing it with my clinician.
_____	I will tell my clinician about all prescription, over-the-counter, supplement, and non-prescribed hormone/anabolic steroid use.
_____	If using gel, I will follow instructions to avoid transfer to partners, children, pregnant people, or pets.
_____	If injecting, I will use sterile technique and dispose of sharps safely.
_____	I will seek medical attention urgently for symptoms such as chest pain, severe shortness of breath, stroke-like symptoms, severe leg swelling, fainting, severe allergic reaction, or pregnancy concern.

Sign _____ Date _____

11. Monitoring plan

I understand that monitoring is part of safer testosterone therapy.

Monitoring item	Baseline	3 months	6 months	12 months	Ongoing
Clinical review of goals, effects, adverse effects	☐	☐	☐	☐	Every 6-12 months or as advised
Blood pressure / weight as appropriate	☐	☐	☐	☐	At routine visits
Hemoglobin / hematocrit	☐	☐	☐	☐	At least yearly once stable or as advised
Total testosterone	☐	☐	☐	☐	Yearly or as clinically indicated once stable
Lipids / HbA1c / glucose if indicated	☐	☐	☐	☐	Based on risk
Liver function if indicated	☐	☐	☐	☐	Based on risk
Pregnancy test if indicated	☐	As needed	As needed	As needed	As needed
STI screening if indicated	☐	As needed	As needed	As needed	As needed
Cervical/chest/breast/other organ-based screening	☐	—	—	—	Per guidelines and anatomy

Testosterone level timing

☐ Injection: level timing explained, including mid-cycle or peak/trough if needed.
☐ Gel: level timing explained, usually after steady daily use and not immediately before application.
☐ Long-acting injection: trough timing explained.
☐ Not applicable today.

12. Preventive health and ongoing screening

I understand that gender-affirming hormone therapy does not replace routine healthcare.

Item	Discussed
Cervical screening if cervix present	☐
Evaluation of abnormal uterine bleeding if uterus/cervix present	☐
Chest/breast screening based on anatomy and surgery status	☐
Ovarian/uterine symptoms should be assessed if organs present	☐
Sexual health and STI prevention	☐
Smoking cessation	☐
Vaccinations	☐
Cardiometabolic risk reduction	☐
Bone health, especially if ovaries removed or testosterone stopped	☐
Mental health support and crisis planning if needed	☐

13. Patient acknowledgement

By signing below, I confirm:

Patient initials	Statement
_____	I have read this form or had it read/explained to me.
_____	I understand the expected benefits, limitations, risks, alternatives, and unknowns of testosterone therapy.
_____	I understand which changes may be irreversible.
_____	I understand the fertility, pregnancy, and contraception issues.
_____	I understand the need for ongoing monitoring and follow-up.
_____	I have had enough time to ask questions.
_____	My questions have been answered to my satisfaction.
_____	I consent to start masculinizing hormone therapy with testosterone.

Sign _____ Date _____

14. Signatures

Patient name: _____
Patient signature: _____
Date / time: _____

Clinician name: _____
Clinician signature: _____
Date / time: _____

Interpreter name, if applicable: _____
Interpreter signature: _____
Date / time: _____

Witness name, if required: _____
Witness signature: _____
Date / time: _____

Parent/guardian name, if legally required: _____
Relationship: _____
Signature: _____
Date / time: _____

15. Clinician attestation

I attest that I have discussed the proposed testosterone therapy with the patient, including expected effects, irreversible changes, alternatives, material risks, fertility preservation, contraception/pregnancy risk, monitoring, and relevant individualized risk factors.

☐ Capacity for informed consent assessed.
☐ Baseline history reviewed.
☐ Baseline examination/vitals reviewed as appropriate.
☐ Baseline investigations ordered/reviewed as appropriate.
☐ Pregnancy risk assessed.
☐ Fertility preservation discussed.
☐ Contraception discussed if relevant.
☐ Follow-up and safety-netting provided.
☐ Patient received a copy of this consent form.

Clinician comments / individualized risk discussion:

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