

Masculinizing Medications for Patients with Gender Dysphoria

Patient Information and Informed Consent

Before starting or continuing treatment with hormones or hormone antagonists, you need to be aware of the effects and possible risks associated with the use of these medications.

The prescribing physician will make a medical decision, in consultation with you, about the medications that are best for you, keeping in mind your overall health during your gender transition process. The effects and possible risks associated with the use of these medications will be discussed with you. It your responsibility to read and understand the following information and raise any questions you have with your prescribing physician.

After your questions or concerns are addressed and you have decided to start or continue hormones or hormone antagonists, you will need to initial the statements below and sign this form.

Medical treatment of people with gender dysphoria is based on very limited, poor-quality research with only subtle improvements seen in some patient’s psychological functioning in some, but not all, research studies. This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments and, in many cases, the need for lifelong medical treatments.

What are the medications that can masculinize one’s appearance?

Treatment with hormones is called hormone replacement therapy or HRT. HRT will require taking testosterone, which increases muscle mass and causes the development of facial hair and a deeper voice. Testosterone when used by biological women, even when the criteria listed below are followed, does not have the U.S. Food and Drug Administration (FDA) approval to be used in the treatment of gender dysphoria and is considered “off label” use because they are not being used for their intended purpose.

Please initial below to acknowledge your understanding of the information on this page.

Patient

How is testosterone taken?

Testosterone is usually injected every one to four weeks. Typically, it is not used as a pill because the body may not absorb it properly and may cause potentially fatal liver problems. The doses used for injection differ from product to product and from patient to patient. The injections are given in the muscle (intramuscular) or can be given with a smaller needle under the skin (subcutaneous). Taking testosterone may cause unwanted swings in hormone levels based on the amount and how often doses are given. Skin creams and patches may also be used. Both testosterone and the treatment process can affect mood. Therefore, individuals must be under the care of a licensed mental health care professional while undergoing treatment.

Finasteride is a treatment option for individuals experiencing bothersome alopecia resulting from higher dihydrotestosterone levels. The administration of 5 α -reductase inhibitors block the conversion of testosterone to the more potent androgen dihydrotestosterone. The FDA approved indications of finasteride administration include benign prostatic hypertrophy and androgenetic alopecia. The use of 5 α -reductase inhibitors may impair clitoral growth and the development of facial and body hair. Future studies are needed to assess the efficacy and safety of 5 α -reductase inhibitors in treatment for gender dysphoria.

Every medication has risks, benefits, and side effects that are important to understand before taking. The effects and side effects of medicines used to treat gender dysphoria must be monitored with laboratory studies and regular visits to the prescribing physician to make sure that there are no negative medical or mental health effects.

What are my other options if I do not wish to start or continue medical treatments?

One option available is psychological therapy with a mental health care provider. This is recommended regardless of whether the individual undergoes treatment with hormones or hormone antagonists or not, due to the high risk of anxiety, depression, self-harm, and suicide. Other options may be discussed with your prescribing physician.

Please initial below to acknowledge your understanding of the information on this page.

Patient

What are the requirements to receive hormone replacement therapy?

To receive hormone replacement therapy, there are specific requirements that need to be met before and during the treatment. These requirements will allow the prescribing physician to monitor medical as well as mental health wellbeing during HRT. If these requirements are not met, HRT may be discontinued by the prescribing physician.

Before beginning HRT and every two years thereafter, the individual needs to undergo a thorough psychological and social evaluation performed by a Florida licensed board-certified psychiatrist or a Florida licensed psychologist. The psychiatrist or psychologist must submit a letter to the prescribing physician confirming this.

The specific requirements for an individual to receive and continue HRT treatment include the following:

1. Has met the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders (DSM) or International Classification of Diseases (ICD);
2. Mental health and physical conditions that could negatively impact the outcome of treatment have been assessed, with risks and benefits discussed;
3. Demonstrates capacity to consent for the specific gender dysphoria hormone treatment;
4. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
5. Has psychological and social support during treatment;
6. Demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of HRT as well as the medical and social risks and benefits of sex reassignment surgery; and
7. Understands the effect of hormone treatment on reproduction and they have explored reproductive options.

Please initial below to acknowledge your understanding of the information on this page.

Patient

The following may also be recommended by your prescribing physician:

1. Undergoes an in-person evaluation by the prescribing physician or their designated covering physician every 3 months for the initial year and at least annually thereafter;
2. Undergoes a suicide risk assessment by a licensed mental health care professional at least every 3 months for the initial year and at least annually thereafter;
3. Undergoes relevant laboratory testing, at least every 6 months;
4. Annual bone scan (DEXA) once a year for the first 5 years to allow monitoring of bone density (bone strength) during treatment, which can be altered by HRT;
5. Annual mental health assessments by a board-certified Florida licensed psychiatrist or psychologist; and
6. Continued counseling with a licensed mental health care professional during the treatment period, with the frequency recommended by the licensed mental health care professional.

Summary of Testosterone Benefits and Risk

BENEFITS	RISKS
<ul style="list-style-type: none"> • Appear more like a man • Bigger clitoris • Coarser skin • Lower voice • More body hair • More facial hair • More muscle mass • More strength • No or minimal menstrual periods • More physical energy • More sex drive 	<ul style="list-style-type: none"> • Acne (may permanently scar) • Blood clots (thrombophlebitis), risk significantly increased by smoking • Emotional changes, for example, more aggression • Headache • High blood pressure (hypertension) • Increased red-blood-cell count • Infertility • Inflamed liver • Interaction with drugs for diabetes and blood thinning — for example Coumadin and Warfarin • Male pattern baldness • More abdominal fat — redistributed to a male shape • Risk of heart disease • Swelling of hands, feet, and legs • Weight gain

Please initial below to acknowledge your understanding of the information on this page.

Patient

Please initial each statement on this form to show that you understand the benefits, risks, and changes that may occur from taking testosterone.

Masculinizing Effects

Patient	Statement
	Testosterone may be prescribed to make me appear less like a female and more like a male.
	It can take several months or longer for the effects of testosterone to become noticeable and no one can predict how fast or how much change will occur.
	<p>The following changes are likely to be permanent even if testosterone is discontinued:</p> <ul style="list-style-type: none"> • Bigger clitoris - typically about half an inch to a little more than an inch • Deeper voice • Gradual growth of moustache and beard • Hair loss at the temples and crown of the head and the possibility of being completely bald • More, thicker, and coarser hair on abdomen, arms, back, chest, and legs
	<p>The following changes could be permanent, but may improve if I stop taking testosterone:</p> <ul style="list-style-type: none"> • Acne (although there may be permanent scars) • Menstrual periods (if present), typically stop one to six months after starting • More abdominal fat – redistributed to a male shape: decreased on buttocks, hips, and thighs; increased in abdomen – changing from “pear shape” to “apple shape” • More muscle mass and strength • More sexual interest • Vaginal dryness • Vaginal Tearing • Vaginal Bleeding • Vaginal Pain • Vaginal infection • Painful intercourse
	This treatment will not change the individual’ s biological sex or chromosomes.
	Testosterone may reduce the ability to become pregnant, but it will not eliminate the risk of pregnancy. A person may become pregnant while on testosterone. I agree to inform the prescribing physician if I become pregnant.
	Some aspects of my body will not change:

	<ul style="list-style-type: none"> • Fat loss may make breasts appear slightly smaller • The voice will deepen, but other aspects of the way I speak may not sound more masculine
	Mood changes may be caused by these medicines, and I will continue therapy with a licensed mental health care professional during treatment.
	Using these medicines to masculinize is an off-label use of the medications. This means these medications are not approved by the FDA for this purpose. I know that the medicine and dose that is recommended is based solely on the judgment and experience of the prescribing physician and there is no data in the medical literature or controlled research studies that support the timing, dosing, and type of administration of HRT.

Risks of Testosterone

Patient	Statement
	Testosterone SHOULD NOT be used by anyone who: <ul style="list-style-type: none"> • Is pregnant • Has uncontrolled coronary artery disease as it could increase your risk for a fatal heart attack
	It should be used WITH CAUTION and only after a full discussion of risks by anyone who: <ul style="list-style-type: none"> • Has acne • Has a family history of heart disease or breast cancer • Has had a blood clot • Has high levels of cholesterol • Has liver disease • Has a high red blood cell count • Is obese • Smokes cigarettes
	The medical effects and the safety of testosterone are not completely known and there may be unknown long-term risks.
	Taking testosterone causes changes that other people will notice.
	Treatment with testosterone will not prevent serious psychiatric events, including suicide.
	Taking more testosterone than prescribed: <ul style="list-style-type: none"> • Will increase health risks; • Will not make changes happen more quickly or more significantly; and • May cause the body to convert extra testosterone into estrogen that can slow down or stop me from appearing more masculine.
	Taking testosterone can cause changes that increase the risk of heart disease. These changes include:

	<ul style="list-style-type: none"> • Less good cholesterol (HDL) that may protect against heart disease and more bad cholesterol (LDL) that may increase the risk of heart disease; • Higher blood pressure; and • More deposits of fat around the internal organs
	Taking testosterone can damage the liver and possibly lead to liver disease.
	Taking testosterone can increase red blood cells and hemoglobin, which may increase my risk of life-threatening problems such as stroke or heart attack.
	Taking testosterone can increase the risk for diabetes (high blood sugars), which decrease the body's response to insulin, cause weight gain, and increase deposits of fat around internal organs increasing the risk of heart disease and stroke.
	Treatment with testosterone can cause ovaries to not release eggs and may cause infertility.
	Treatment with testosterone increases the risk of cancer to the uterus, ovaries, or breasts. It is unclear if taking testosterone plays any role in HPV infection or cervical cancer.
	Taking testosterone causes or worsens migraines.
	Taking testosterone can cause emotional changes, such as irritability, frustration, aggression, and anger.

Risks of Finasteride

Patient	Statement
	Finasteride may be an appropriate treatment option in individuals experiencing bothersome alopecia resulting from testosterone treatment.
	Finasteride may have side effects which include: <ul style="list-style-type: none"> • decreased libido • dry skin • acne • Breast swelling and tenderness • headache • irregular menstruation • dizziness • increased body hair
	Finasteride is not approved by the FDA for use in biological women and is forbidden in pregnant women due to birth defects.

Requirements of Treatment with HRT

Patient	Statement
	Compliance with the requirements explained above is a prerequisite to receive treatment with testosterone.
	The prescribing physician may stop prescribing testosterone if the prescribing physician or mental health care professionals providing treatment pursuant to this consent determine the benefit of treatment no longer outweighs the risks, there is insufficient social or psychological support, or the requirements in this consent are not met.
	I understand that I may decide to stop treatment at any time.

Prevention of Complications while under Treatment of HRT

Patient	Statement
	I agree to notify the prescribing physician if I suffer from any side effects during treatment or am unhappy with the treatment in any way, and if I have any concerns that I have worsening signs of depression or anxiety or wants to harm myself or attempt suicide or attempt suicide.
	The prescribing physician is required to monitor me for any side effects during treatment and may refer me to another physician or specialist for treatment.

CONSENT:

My signature below confirms that:

1. My prescribing physician has talked with me about:
 - a. the benefits and risks of taking testosterone;
 - b. the possible or likely consequences of hormone therapy; and
 - c. potential alternative treatments.
2. The information provided to me in this form and by the prescribing physician includes the known effects and risks of treatment with testosterone. I know that there may be other unknown short-term and long-term effects or risks which may be irreversible.
3. I have had sufficient time and opportunity to discuss relevant treatment options with my prescribing physician.
4. All my questions have been answered to my satisfaction by my prescribing physician.
5. I know enough to give informed consent to take, refuse, or postpone taking testosterone.

6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your physician.
7. My signature below attests to my consent to begin treatment with testosterone.

Based on all this information:

- _____ I want to begin or continue taking testosterone
- _____ I want to begin or continue taking finasteride
- _____ I do not wish to begin or continue taking masculinizing medication

Patient's printed name (required)

Patient's signature (required)

Date

PRESCRIBING PHYSICIAN:

My signature below attests to my compliance with 456.52, Florida Statutes.

Prescribing physician's printed name (required)

Prescribing physician's signature (required)

Date

WITNESS:

Witness' printed name (required)

Witness' signature (required)

Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

I certify that I am fluent in English and in the native language of the person indicating consent and/or assent on the above form. I certify that I have accurately and completely interpreted the contents of this form, and that the patient has indicated understanding of the contents of this form.

Interpreter's printed name

Interpreter's signature

Date