

Masculinizing Medications for Patients with Gender Dysphoria

Patient Information and Informed Parental Consent and Assent for Minors

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

After your questions or concerns are addressed and you have decided to have the minor start or continue treatment with hormones or hormone antagonists, a parent/legal guardian and the minor must initial the statements below and sign this form. Both the parent/legal guardian and the minor must sign in person.

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 minors, even when the criteria listed below are followed, does not have U.S. Food and Drug Administration (FDA) approval to be used by minors and its use in this population is considered “off label” because they are not being used for their intended purpose.

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

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

What are my other options if I do not wish to start or continue my minor’s treatment with hormones or hormone antagonists?

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

How is testosterone taken?

Testosterone is usually injected every one to four weeks. Typically, it is not given in pill form because the body may not absorb it properly which 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). A minor taking testosterone may experience unwanted swings in hormone levels based on the amount and how often doses are given.

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 minor’s prescribing physician to make sure that there are no negative medical or mental health effects.

Both testosterone and the treatment process can affect a minor’s mood. Therefore, minors must be under the care of a licensed mental health care professional while undergoing treatment. This professional can work with the minor, your family and friends, and your school staff.

What are the requirements to receive hormone replacement therapy (HRT)?

To receive HRT, there are specific requirements that need to be met before and during treatment. These requirements will allow the prescribing physician to monitor the minor’s medical and mental health status during treatment. If these requirements are not met, HRT may be discontinued by the prescribing physician.

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Before beginning or continuing HRT, a minor 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 a minor 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. Has pubertal changes resulting in an increase in gender dysphoria;
3. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
4. Has psychological and social support during treatment;
5. Has experienced puberty to at least Tanner Stage 2 (first stage of puberty), which must be confirmed by a physician;
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;
7. Undergoes an in-person evaluation by the prescribing physician or their designated covering physician at least every 6 months;
8. Undergoes a suicide risk assessment by a licensed mental health care professional at least every 3 months;
9. Undergoes relevant laboratory testing, at least every 4 months;
10. X-ray of the hand (bone age) at least once a year if the minor is still growing;
11. Annual bone density scan (DEXA) which will allow monitoring of the minor’s bone density (bone strength) during treatment, which can be altered by HRT
12. Annual mental health assessments by a Board-certified Florida licensed psychiatrist or psychologist; and
13. Continued counseling with a licensed mental health care professional during the treatment period, with the frequency recommended by the licensed mental health care professional.

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

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Summary of Testosterone Benefits and Risks

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 such as 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.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

Please initial each statement on this form to show that you understand the benefits, risks, and changes associated with a minor taking testosterone.

Masculinizing Effects

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Testosterone may be prescribed to make a minor 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.
			Changes from testosterone may not be complete for 2 to 5 years after treatment is started.
			<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 minor’s biological sex or chromosomes.
			Testosterone may reduce the minor’s ability to become pregnant, but it will not eliminate the risk of pregnancy. A person can become pregnant while on testosterone. I agree to inform the minor’s prescribing physician if the minor becomes pregnant.
			Some aspects of the minor’s body will not change: <ul style="list-style-type: none"> • Fat loss may make breasts appear slightly smaller (if present) • The voice will deepen, but other aspects of the way the minor speaks may not sound more masculine
			Mood changes may be caused by these medicines, and the minor will continue therapy with a licensed mental health care professional during treatment.
			Using these medicines to masculinize a minor 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 minor’s 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 for minors.

Risks of Testosterone

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	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
			Testosterone 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

			<ul style="list-style-type: none"> • Has a high red blood cell count • Is obese • Smokes cigarettes or uses tobacco products
			The medical effects and the safety of minors taking 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.
			<p>The minor must not take more testosterone than prescribed. Taking too much testosterone:</p> <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 the minor appearing more masculine
			<p>Taking testosterone can cause changes that increase the risk of heart disease into adulthood. These changes include:</p> <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 worsen migraines.

			Taking testosterone can cause emotional changes, such as irritability, frustration, aggression, and anger.
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Requirements of Treatment with HRT

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Compliance with the requirements explained above is a prerequisite for a minor 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.
			The parent/guardian or the minor can change their mind and stop treatment at any time although some effects of HRT may be permanent.

Prevention of Complications while under Treatment with HRT

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			The undersigned parent(s)/legal guardian(s) agree(s) to notify the minor's prescribing physician if the minor suffers from any side effects during treatment or is unhappy with the treatment in any way, particularly if the parent(s)/legal guardian(s) has/have any concerns that the minor has worsening signs of depression or anxiety or expresses a desire harm themselves or attempt suicide.
			The prescribing physician is required to monitor the minor for any side effects during treatment and may refer the minor to another physician or specialist for treatment. The undersigned parent(s)/legal guardian(s) agree(s) to take the minor physicians and specialists as recommended by the prescribing physician.

PARENTAL CONSENT:

The signature(s) below confirm(s) the following:

1. The minor's prescribing physician has fully informed 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 the minor's prescribing physician.
4. All my questions have been answered to my satisfaction by the minor's prescribing physician.
5. I know enough to give informed consent for the minor 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 for the minor to begin treatment with testosterone.

Parent/legal guardian's printed name (required)

Parent/legal guardian's signature (required)

Date

Parent/legal guardian's printed name (optional)

Parent/legal guardian's signature (optional)

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

ASSENT OF A MINOR:

I have discussed the benefits and risks of treatment with masculinizing medication with my prescribing physician, parent(s) or legal guardian(s), and I wish to receive it.

Minor's printed name (required)

Minor'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 and/or adult(s) legally responsible for the minor child has indicated understanding of the contents of this form.

Interpreter's printed name

Interpreter's signature

Date