



JGLHC Gender-Affirming Hormone Therapy

Testosterone Informed Consent Form

Here at the Lovering Health Center, we strive to offer patient-centered gender-affirming care that prioritizes patients' goals, satisfaction with treatment, and safety. Through informed consent and shared decision-making, every effort will be made to support and involve you in your care. Informed consent is a continuous, ongoing decision-making process based on your voluntary decision to engage in medical treatment, which is based on having full knowledge and understanding of said treatment. The purpose of this informed consent form is to help you consider the risks, benefits, and alternatives so that you can make a fully informed decision to consent to hormone therapy. The use of hormone therapy for gender affirmation is based on our years of clinical experience, clinical collaboration, and ongoing evidence-informed standards. As of now, gender-affirming hormone therapy is not FDA approved and it is still considered "off label." Research on this hormone therapy is slowly providing us with more information on its safety and efficacy over time, but long-term effects of the therapy are not yet fully understood.

Testosterone as gender-affirming hormone therapy

Testosterone can be provided as an injection into the muscle or subcutaneous tissue, or as a gel or cream. Your provider will work with you to find the medication and dose that is best suited for you and your body.

Forms of testosterone

Testosterone cypionate/enanthate

- Testosterone cypionate contains cottonseed oil, while testosterone enanthate contains sesame oil. One may be substituted for the other in case of allergy.
- Given either by intramuscular or subcutaneous injection
- An injection training is provided here at Lovering before starting.
- Injections are usually done once weekly, but may be done semi-weekly or bi-weekly.

Topical testosterone

- Applied to the skin daily
- Available in concentrations of 1% or 1.62%, or via compounded formulations (depending on patient needs and financial coverage)
- Education about safety with skin-to-skin contact with other people/pets is important.
- Physical changes may be more gradual in comparison with injectable testosterone.

Potential effects of testosterone as gender-affirming hormone therapy

There can be a wide range of variation between peoples' goals for their transition and their responses to hormone therapy, and it can be hard to predict how much or how fast these changes will happen. The

rate and degree of change is largely dependent upon one's genetics, one's previous exposure to estrogen, and individual variations in response. The changes in the body may take several months to first become noticeable, and they may take 3-5 (or more) years to become "complete" (a term that each person defines differently, depending on personal goals). While some changes are permanent, other changes are not permanent, and someone may want to continue to utilize testosterone as a tool to maintain those non-permanent changes.

Permanent changes (may not go away completely, even if you stop the medication)

- Increased facial and body hair
- Deepened voice
- Enlargement of the clitoris
- Hair loss (potentially male-pattern baldness)

Non-permanent changes (will likely reverse over time if hormone therapy is stopped)

- Increased sex drive
- Body fat redistribution (to the abdomen rather than to the buttocks, hips, and thighs)
- Increased muscle development (often dependent on exercise and/or lifestyle)
- Cessation of menstrual periods

Risks and potential side effects of testosterone

Usually, the benefits of testosterone for gender affirmation outweigh the risks for most people. However, there are some potentially serious risks of testosterone use, as described below:

- Increased blood pressure, or increased risk of developing hypertension
- Increased fat or cholesterol in the blood. HDL or "good" cholesterol may decrease and LDL or "bad" cholesterol may increase.
- Increased fat deposits around the heart, blood vessels, and other organs
- Increased risk of developing excess red blood cells. It is normal to have an increase in red blood cells and hemoglobin, but if these levels become higher than what would be considered "normal" for someone assigned male at birth, the risk of developing blood clots may increase. Thus, you will have regular lab work to monitor the hemoglobin and/or the red blood cells.
- Harm or damage to the liver (this is not common when testosterone is given as an injection)
- Increased risk of developing diabetes by causing a decrease in the body's response to insulin
- Changes in mood, especially during the first 6 months of treatment. This change may feel positive, negative, or a mix of both. Many people report feeling irritable, angry, or more impulsive. However, most people find that their overall mental health improves after starting hormone therapy. Discuss this topic with your provider because we can also refer you to resources that offer emotional support.

- Conversion to estrogen (aromatization) if testosterone levels become significantly elevated. It's not known if this process increases your risk of developing cancers of the breast, the ovaries, or the uterus.

The risks of testosterone therapy are greater for people who

- Smoke cigarettes/use tobacco or nicotine products;
- Are older than 40;
- Have heart disease, high blood pressure, high cholesterol, or a history of blood clots;
- Have a family history of breast cancer; and/or
- Have liver disease or hepatitis.

Smoking cigarettes and/or the use of other tobacco/nicotine products may greatly increase the risks of taking testosterone, especially the risk of blood clots and heart disease. If you are a current smoker, it is important for your health to make an effort to quit or cut back. If you need additional support with quitting/cutting down, you can talk to your provider about strategies and/or medications to help you.

How does testosterone affect my fertility?

Testosterone is likely to affect your ovulation cycles, although it is not known exactly how long this takes to happen, to what degree, and whether or not the changes are permanent. Even if you stop taking testosterone, it is possible that you may not be able to become pregnant in the future. For this reason, you may choose to undergo gamete (egg) banking before starting hormone therapy if having biological children is something that may be important to you in the future.

Although hormone therapy can affect your fertility, it is still possible that you could become pregnant while you are taking testosterone. If you currently have or could potentially have a sexual partner with whom you have reproductive potential and you are not seeking pregnancy, it is important to use another method of contraception to prevent pregnancy, such as condoms. Testosterone is a medication that is considered teratogenic, or has the potential to harm a developing fetus. For this reason, it is often recommended that a reliable form of contraception be used in addition to condoms.

Besides hormone therapy with testosterone, what are my other choices for gender-affirming care?

- Gender-affirming surgical procedures
- Use of chest binders, packers, or cosmetic products
- Voice training/vocal coaching

Once you begin testosterone as gender-affirming hormone therapy

In the first year of starting gender-affirming hormone therapy, you will have

- An initial appointment, which may be via telehealth;



- A second appointment in person so that we can perform lab work as indicated;
- An injection training visit (if starting on an injectable form of testosterone); and

- Follow-up visits every 3 months (or sooner, if desired) until you and your provider feel that your dosing and satisfaction are stable. Thereafter, you will have follow-up visits every 6-12 months. For each visit, your provider will discuss with you what lab work is necessary and why.

Your provider will always intend to give enough medication to get you to your next scheduled appointment, so if you're running low on your meds, that means you're probably due for a visit. If you are running low on your meds, do not have refills, and don't have a visit scheduled (or have a visit scheduled after you will run out of meds), give us a call.

Communication with your provider

In order to offer you the best care that we can, it is our hope that you will communicate directly and clearly with us throughout your care. Therefore, we ask that you

- Inform your medical provider about any new medications (including dietary or herbal supplements) you are taking and updated doses of medications (prescribed or not prescribed), so we can discuss possible interactions with and effects on your hormone treatment;
- Inform your provider of any new symptoms or medical conditions that may develop; and
- Keep regular follow-up appointments and get necessary lab work done.
- **Call the office at (603) 436-7588 if you are noticing any of the following symptoms:**
 - Headaches that are new, persistent, debilitating, or causing visual changes
 - Mood changes, such as worsening depression, anxiety, or mania that appears extreme (especially if you have pre-existing mental health conditions), or thoughts of harming yourself or others
 - Pregnancy symptoms, such as nausea, vomiting, tenderness in breast tissue, frequent urination, or unusual fatigue. Either take a pregnancy test at home or come into the office for evaluation if you are or think you could be pregnant.
- **Call 911 immediately if you are having any of these severe symptoms:**
 - Any signs of a heart attack or PE (blood clot in the heart or lung): chest pain, shortness of breath/difficulty breathing, palpitations
 - Any signs of a stroke: one-sided weakness, facial drooping on one side of the face, difficulty speaking, understanding, and walking
 - Any signs of a DVT (blood clot in the leg): pain in the leg, accompanied by swelling and localized heat
 - **Call your provider once you are safe and stable**, so they can support you with follow-up care.



Discontinuation of hormone therapy

You can choose to stop testosterone at any time. If you decide to stop testosterone, talk to your provider so they can support you. Suddenly stopping testosterone after you have been taking it for a long time may have negative health effects, so you are encouraged to discuss this decision with your medical provider.

By signing this form, you acknowledge

- You are at least 18 years of age;
- You have been given adequate information to be able to make an informed decision about voluntarily undergoing gender-affirming hormone therapy;
- You understand the information your provider has given you, and you have been given an opportunity to ask any questions regarding the contents of this form and the treatment you're about to begin; and
- You consent to receiving gender-affirming hormone therapy.

_____	_____
Name of patient	Date of birth
_____	_____
Signature of patient	Date
_____	_____
Signature of witness	Date