



## **JGLHC Gender-Affirming Hormone Therapy**

### **Estrogen and/or Anti-Androgen 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.*

#### **Estrogen and/or anti-androgens as gender-affirming hormone therapy**

Historically, estrogen is used alone or in combination with an anti-androgen medication to bring about certain changes in the body. The anti-androgen medication that we typically prescribe at the Lovering is called spironolactone, which is a blood-pressure-lowering medication that also blocks and lowers testosterone. Spironolactone is formulated as a tablet that is typically taken daily by mouth, and is discussed in more detail below. The type of estrogen we typically use for gender affirmation is estradiol, which is bioidentical (structurally similar to the hormones that are made within our bodies, which is different from the chemical structures of other synthetic estrogens that are used for contraception), and generally considered to be safer than other synthetic estrogens.

Estradiol can be provided in several formulations: a pill that you put under the tongue, a patch that is put on the skin, or a shot into the muscle or subcutaneous tissue. Your provider will work with you to find the medication and dose that is best suited for you.

#### ***Forms of estradiol***

##### **Estradiol patches**

- Adhesive patches are applied to the skin once or twice weekly.
- Thought to be the safest mode of delivering estrogen to the body
- Physical changes may be more gradual in comparison to injections and tablets.

##### **Estradiol tablets**

- We recommend taking tablets sublingually for better bioavailability and to avoid some of the first-pass metabolism through the liver (as opposed to swallowing pills by mouth).



- Generally accessible, affordable, and easiest to get covered by insurance
- Short half-life, which means they are intended to be taken multiple times per day

Estradiol injections (estradiol valerate or estradiol cypionate)

- Given either by intramuscular or subcutaneous injection
- Injection training is provided here at Lovering before starting.
- Injections are usually done once weekly, but may be done semi-weekly or bi-weekly.
- We require lab work to check estradiol levels every 2-3 months. For further information, please review our separate educational sheet about estradiol injections.

### **Potential effects of estrogen and/or anti-androgens**

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 on one's genetics, one's previous exposure to testosterone, 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 estrogen and/or spironolactone as a tool to maintain those non-permanent changes.

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

- Breast growth and development
- The testicles become smaller and softer
- Decreased sperm production and potential infertility (unable to create a pregnancy)

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

- Fat redistribution to the buttocks, hips, and thighs rather than to the abdomen and mid-section
- Loss of muscle mass and decreased strength, particularly in the upper body
- Softening of skin and decreased acne
- Softening, lightening, and slower growth of facial and body hair
- Slowing/stopping of head hair loss (but hair generally won't grow back in that area)
- Sexual changes: reduced sex drive; the inability to achieve or maintain an erection; decreased strength, frequency, and duration of erections; decreased ejaculate and/or change in consistency, taste, or color of ejaculate
- Changes in mood or thinking, like increased emotional access or reactivity, which may feel positive, negative, or a mix of both. 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.

## **Risks and possible side effects of both anti-androgen medication (spironolactone) and estradiol**

Usually, the benefits of hormone therapy for gender affirmation outweigh the risks for most people. The risks of estrogen are different from the risks of spironolactone, and both are reviewed separately below.

### ***Spironolactone can create the following effects:***

- Increased urine production and change in kidney function, which can cause a feeling of needing to urinate more frequently and sometimes a noticeable increase in thirst
- Decreased blood pressure, which can also cause a feeling of lightheadedness or dizziness
- Increased potassium in the blood, which typically doesn't cause noticeable side effects. However, if the potassium level gets too high, it can lead to muscle weakness, nerve problems, and dangerous heart arrhythmias (irregular heart rhythms) that can be life-threatening. You will have regular lab work to check kidney function and potassium levels.

### ***Estrogen can create the following effects:***

- Increased risk of developing blood clots. Depending on where it travels in the blood vessels, a blood clot can cause a heart attack, a stroke, a DVT (blood clot in the leg), a PE (blood clot in the lung), or a blood clot in another area of the body.
- Increased blood pressure
- Increased fat or cholesterol in the blood
- Increased risk of heart disease
- Increased risk of developing diabetes
- Increased risk of gallbladder problems
- New or worsened migraine headaches
- A milky discharge from one or both nipples, called galactorrhea
- Prolactinoma, which is a non-cancerous tumor on the pituitary gland that produces too much of the hormone prolactin and can cause a milky discharge to come from the nipples
- Changes in sexual function such as decreased libido, the inability to achieve or maintain an erection, and potential changes in fertility (the ability to create a pregnancy)
- Harm to the liver
- Mood swings or, in rare cases, worsened depression
- Increased risk of developing breast cancer

### ***The risks of estrogen 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 estrogen, 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 estrogen and/or spironolactone affect my fertility?**

Taking estrogen and/or spironolactone can change your body's ability to make healthy sperm, but how long this effect takes to happen and whether it becomes permanent can vary. For this reason, you may choose to bank some of your sperm 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 create a pregnancy. If you 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.

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

- Gender-affirming surgical procedures
- Laser hair removal/electrolysis
- Use of cosmetic products and/or makeup
- Voice training/vocal coaching
- Use of breast forms/breast prosthesis
- Use of waist cinchers or girdles
- Use of wigs or hair prosthesis

### **Once you begin estrogen and/or spironolactone 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 estradiol); 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
  - A milky discharge coming from one or both nipples
  - Visual changes (including loss of peripheral vision) with or without headache
- **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 taking these medications at any time. If you decide to stop the medications, talk to your provider so they can support you. Suddenly stopping estrogen and/or anti-androgen medications after you have been taking them 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 receive gender-affirming hormone therapy.

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Name of patient

\_\_\_\_\_  
Date of birth

\_\_\_\_\_  
Signature of patient

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of witness

\_\_\_\_\_  
Date