

## **Patient Information and Informed Consent for Minors**

Before using medications to transition your adolescent to their affirmed gender, you need to be aware of the possible advantages, disadvantages, and risks of these medications. We have listed them here for you. And you are also encouraged to do your own research on the subject.

Once your questions or concerns are addressed, and you have decided to proceed with the medication(s), you will need to sign this information and consent form, as well as have your signatures notarized. If there is more than one parent/legal guardian, both will have to sign. Your child will also need to sign this form.

### **What are the different medications that can masculinize one's appearance?**

Part of transition for many transgender people involves taking hormones, this is also called hormone replacement therapy or HRT. HRT in transgender boys and men means taking androgens (male hormones), and possibly also medicines to block their body from producing or utilizing estrogen (female hormones). Use of these medications in adolescents with gender dysphoria is considered “standard of care” as long as they also meet specific criteria listed below, but these medications do not have the FDA indication to be used in this population. In other words, it is “off label use.”

Different forms of the hormone testosterone are used to masculinize appearance in transgender males. Testosterone can be given as an injection to be given weekly, a gel applied daily, or even a patch. Many times the topical forms (gel and patches) are prohibitively expensive, however.

Medications that block the production or effects of estrogen are commonly referred to as estrogen blockers. Estrogen is another term for female sex hormones. Anastrozole is used for this purpose, and is taken once daily. Generally this medication is utilized only in the first few months of therapy, but sometimes it needs to be continued for longer.

Every medication has risks, benefits, and side effects that are important to understand before starting. The effects and side effects of medicines used for transition need to be monitored with laboratory studies and regular visits to your child's provider, to make sure that there are no negative medical and mental health effects.

Both Estrogen and Anastrozole, as well as the process of transitioning, can affect your adolescent's mood. While trans men are usually relieved and happy with the changes that occur, we recommend that your child continue the care of a gender-qualified therapist while undergoing transition. The therapist can work with your child, your family and friends, and your school staff.

### **Alternatives**

There are alternatives to using masculinizing medicines to help people appear more masculine. Some people eventually have surgical procedures to alter appearance and bodily functions. Other

transgender people choose to not take hormones or have surgery at all, and may only “socially transition.” This is just as equally valid as the medical forms of transitioning.

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

In order to receive hormone replacement therapy (HRT) in our program, there are specific requirements that need to be met before and during the treatment. Although this therapy is considered standard of care, this is a new area of medicine for adolescents, and we want to provide the safest treatment possible. These requirements will allow us to monitor your child’s medical as well as mental health wellbeing during HRT. If these requirements are not met, HRT may be discontinued in the best interest and safety of your child.

After all this has taken place, HRT can be initiated if your child meets the criteria established by the Endocrine Society and our own clinic standards:

1. Fulfill the current criteria for a diagnosis of gender dysphoria and have received a letter of referral for hormone initiation from a therapist (form provided if needed).
2. Have completed a routine physical with a healthcare provider (form will be provided).
3. Have signed/notarized consent of all adult parties who are legally responsible for them.
4. Have pubertal changes that have resulted in an increase in gender dysphoria.
5. Do not suffer from psychiatric comorbidity that interferes with hormone therapy.
6. Have adequate psychological and social support during treatment. We recommend continuing therapy services throughout at least the first year of transitioning.
7. Have experienced puberty to at least Tanner stage 2 (first stage of puberty).
8. Is at least 16 years of age prior to beginning hormone therapy.

After HRT has been initiated, the following will be required:

1. Laboratory testing every 3 months, or as determined by the provider.
2. Visits with the healthcare provider every 3 months, or as determined by the provider.

What are the effects and risks of using these medications?

Testosterone should not be used by anyone who has a history of:

- A testosterone-dependent cancer.

- A disorder that makes them more likely to get blood clots that could travel to the lungs (unless they are also taking blood thinners and are followed by a specialist).

Testosterone should be used with caution and only after a full discussion of risks by anyone who:

- - Has poor overall physical health
- - Has heart disease
- - Has chronic hepatitis or other liver disease
- - Has uncontrolled high cholesterol
- - Has migraines or seizures

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

#### Effects of Masculinizing Medications

\_\_\_\_\_ I know that testosterone, estrogen blockers, or both may be prescribed to masculinize my adolescent's appearance.

\_\_\_\_\_ I know it can take several months or longer for the effects to become noticeable. I know that no one can predict how fast – or how much – change will happen.

\_\_\_\_\_ I know that taking testosterone will cause the following changes to my adolescent:

- Breast tissue may atrophy, if present, or may fail to form if not present yet
- Enlargement of the clitoris and deepening of the voice
- Skin may be thicker, oily, and more susceptible to acne
- Menstrual cycle will likely stop altogether
- Facial hair such as a beard and mustache will grow

\_\_\_\_\_ I know that the following changes are usually not permanent:

- Body hair will thicken, darken, and grow faster (facial hair is permanent, however).
- Increases in muscle and strength as their muscle mass adjusts to that of a more masculine physiology.
- Fat deposits will align into a more masculine outline.

\_\_\_\_\_ I know that my adolescent's body will make less estrogen. This may affect:

- The vaginal canal tissue may atrophy, making it potentially more susceptible to a UTI or Yeast infections.
- Eggs may no longer get to mature. This could make your adolescent less likely to be able to have children while taking hormones, and it may be a permanent change even if hormone therapy is discontinued.
- However, it is also possible that the eggs could still mature even while taking hormones. Therefore, I understand that my adolescent may still be able to get pregnant. Usual sexual health precautions still need to be taken during sexual activity.

\_\_\_\_\_ I know that there may be mood changes with these medicines.

\_\_\_\_\_ I know that using these medicines to feminize is an "off-label use." This means it is not an approved use by the Food and Drug Administration (FDA). I know that the medicine and dose that is recommended is based on the judgment and experience of my child's healthcare provider and the best information that is currently available in the medical literature.

#### Further Risks of Masculinizing Medications (Testosterone and Estrogen Blockers)

\_\_\_\_\_ I know that the side effects and safety of these medicines are not yet completely known when used for medical transitioning. There may be long-term risks that science is as of yet unaware of.

\_\_\_\_\_ I realize that this treatment may not be able to completely prevent serious psychiatric events such as a suicide attempt or other self-harm.

\_\_\_\_\_ I know that my child should not take more medicine than prescribed.

\_\_\_\_\_ Taking too much medication will increase health risks. It also will not make changes happen more quickly or more significantly.

\_\_\_\_\_ I know these medicines may cause liver damage over time. Therefore, your child should be checked for possible liver damage periodically as long as they take the medications.

\_\_\_\_\_ I know these medicines cause changes that other people will notice. Some transgender people have experienced discrimination because of this.

\_\_\_\_\_ I understand that the long terms effects of hormone therapy on bone density are not quite understood yet.

\_\_\_\_\_ I know that testosterone can possibly make migraines or seizures worse if my child already has them.

### Further Consent

\_\_\_\_\_ I understand and agree with all the requirements explained above, in order to receive HRT in our program.

\_\_\_\_\_ I know that the mental health team and/or treating physician may recommend to stop treatment because it no longer outweighs the risks, there is insufficient social or psychological support, or our program requirements to treat are not met. In this case, we will not continue to prescribe hormone therapy.

\_\_\_\_\_ I know that I am responsible for the cost of medical management, including medical appointments, psychological evaluations, laboratory and imaging tests, as well as medications.

\_\_\_\_\_ I know that I can change my mind and decide to stop treatment at any time.

### Prevention of Complications while under Treatment of HRT

\_\_\_\_\_ I agree to tell my health care provider if my child has any problems or side effects or is unhappy with the medication, and in particular, if you have concerns that your child has worsening signs of depression or anxiety, or wants to harm themselves or attempt suicide.

\_\_\_\_\_ I know my child needs periodic medical evaluations clinic to make sure that my child is responding appropriately. This includes clinic visits, laboratory tests, and imaging tests.

\_\_\_\_\_ I agree that if my child's therapist recommends continued psychological therapy or counseling that we will follow their guidance.

\*Our signatures below confirm that my clinician has talked with me and my child about:

-The benefits and risks of taking feminizing medication

-The possible or likely consequences of hormone therapy

-Potential alternative treatments

-I understand the risks that may be involved

-I know that the information in this form includes many known effects and risks. I also understand that there may be unknown long-term effects or risks.

-I have had opportunity to discuss treatment options with our child's clinician.

-My child is in agreement with this treatment and the signature of my child on the assent form attests to their agreement.

-All of my questions have been answered to my satisfaction

**CONSENT OF PARENT(S)/GUARDIAN(S):**

**I believe I know enough to give informed consent for starting my adolescent child on masculinizing medications. Based on all of this information, I want my adolescent child to begin taking hormone therapy, including testosterone and/or estrogen blockers. My signature below consents to this. (If second parent/guardian signature will not be used, mark it out with a line or write in "N/A")**

\_\_\_\_\_ Parent's Name (printed)

\_\_\_\_\_ Parent's Signature

\_\_\_\_\_ Date

\_\_\_\_\_ 2nd Parent (printed), if applicable

\_\_\_\_\_ Parent's Signature

\_\_\_\_\_ Date

**ASSENT OF MINOR:**

**I have discussed the benefits and risks of treatment with my parent(s)/guardian(s) as well as my clinician, and I wish to begin masculinizing hormone therapy.**

\_\_\_\_\_ Minor's Name (printed)

\_\_\_\_\_ Minor's Signature

\_\_\_\_\_ Date

**NOTARY SECTION:**

The preceding parent/guardian signatures on this page were witnessed in my presence

on this \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_\_.

\_\_\_\_\_, Notary Public

State of \_\_\_\_\_. County of \_\_\_\_\_.

My Commission Expires: \_\_\_\_\_.