

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 feminize 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 girls and women means taking estrogens (female hormones), and possibly also medicines to block their body from producing or utilizing testosterone (male 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 estrogen are used to feminize appearance in transgender females. Estrogen can be given as an injection to be given weekly, as a pill to be taken several times a day, or as a patch to be changed every three or four days.

Medications that block the production or effects of testosterone are called androgen blockers. Androgen is another term for male sex hormones. Bicalutamide is used for this purpose, and is taken once daily. Your child may or may not need to stay on this for the duration of their therapy.

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 Bicalutamide, as well as the process of transitioning, can affect your adolescent's mood. While trans women 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 feminizing medicines to help people appear more feminine. 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 consent of all 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?

Estrogen has a small chance of causing blood clots in some individuals. We must be careful that your child is not at risk to develop a blood clot.

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

- An estrogen-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).

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

- - Has a strong family history of breast cancer or other cancers that grow quicker when estrogens are present
- - Has uncontrolled diabetes
- - Has heart disease
- - Has chronic hepatitis or other liver disease
- - Has uncontrolled high cholesterol
- - Has migraines or seizures
- - Is obese
- - Smokes tobacco

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 Feminizing Medications

_____ I know that estrogen, anti-androgens, or both may be prescribed to feminize 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 estrogen will cause the following changes to my adolescent's chest:

- Will develop breasts.
- It takes several years for breasts to get to their full size.
- The breasts will remain, even if estrogen is stopped, though they may atrophy.

- A milky discharge from the nipples may appear. If this happens, it may be normal, but this should be checked with your child's provider.

* While we do not know the exact risk, the risk of breast cancer may be as high as if your child had been assigned female at birth.

_____ I know that the following changes are usually not permanent — they are likely to go away if the medicines are stopped:

- If body hair is present, it will become less noticeable and will grow more slowly although it won't stop completely, even after taking medicines for years.
- There might be less fat on the abdomen and more on the buttocks, hips, and thighs. The fat will be redistributed to a more feminine shape.
- Your child may lose muscle and strength in the upper body as their muscle mass adjusts to that of a more feminine physiology.
- The skin may become softer.

_____ I know that my adolescent's body will make less testosterone. This may affect:

- The testicles may shrink down to half their size.
- It is likely that there will be fewer spontaneous erections.
- Sperm may no longer get to mature. This could make your adolescent less likely 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 sperm could still mature even while taking hormones. Therefore, I understand that my adolescent may still be able to cause a pregnancy. Usual sexual health precautions still need to be taken during sexual activity.
- The options for sperm banking have been explained.

_____ I know that some parts of the body will likely not change much by using these medications.

- If present, the hair of the beard and mustache may grow more slowly than before. It may become less noticeable, but it will not go away with hormone therapy alone.

- If your child went through a “male puberty” and has a “male voice,” the pitch of the voice will not rise, and the speech patterns will not become more like a woman’s without either voice training or surgical alteration.
- If present, the “Adam’s apple” will not shrink.

_____ 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 approved 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 Feminizing Medications (Estrogen and Anti-Androgens)

_____ I know that the side effects and safety of these medicines are not yet completely known. 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 know that the risk of blood clots is much worse if my child smokes cigarettes.
*The danger is high enough that your child should stop smoking completely if estrogen is started.

_____ I know that taking estrogen can increase the risk of getting gallstones, and I should talk to our child’s clinician if unexplained pain in the abdomen occurs.

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

_____ I know that estrogen can possibly make migraines or seizures worse if my child already has them.

_____ I understand that it is not yet known if taking estrogen increases the risk of prolactinomas. These are non-cancerous tumors of the pituitary gland. I know they are not usually life threatening, but they can damage vision and cause headaches if they are not treated properly. Therefore, if your child has changes in vision, or headaches that are worse when waking up in the morning, I should talk to my child's provider. There is a blood test that can check for this.

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 the 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 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 feminizing medications. Based on all of this information, I want my adolescent child to begin taking hormone therapy, including estrogen and/or anti-androgens. 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 feminizing 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: _____.