

GENder Education and Care Interdisciplinary Support (GENECIS)

Feminizing Medications for Patients with Gender Dysphoria

Patient Information and Informed Consent and Assent for Minors

Before using medications to transition your adolescent to her/his affirmed gender, you need to be aware of the possible advantages, disadvantages and risks of these medications. We have listed them here for you.

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. If there is more than one parent/legal guardian, both will have to sign. Your child will also need to assent 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), as well as 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 or every other week, as a pill to be taken daily or twice 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. Spironolactone is the androgen blocker that is most commonly used in the United States. Other medicines are sometimes used, but because spironolactone is relatively safe, inexpensive, and effective to block testosterone, it is the primary androgen blocker used for transgender women.

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 these medicines, as well as the process of transitioning can affect your adolescents' mood. While trans women are usually relieved and happy with the changes that occur, it is important that your child is under 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 transgender people choose to not take hormones or have surgery and may only socially transition. If you are interested in alternatives, talk with your adolescent's health care provider about options.

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.

Before beginning HRT your child needs to undergo a thorough psychological and social evaluation performed by our GENECIS team. We also require your child has participated in at least 6 months of psychological therapy. We will need a letter from your child's therapist confirming this.

After all this has taken place, HRT can be initiated if your child meets the criteria established by the Endocrine Society, which includes ALL of the following:

1. Fulfill the current DSM or ICD criteria for gender dysphoria or transsexualism.
2. Have pubertal changes that have resulted in an increase in gender dysphoria.
3. Do not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment.
4. Have adequate psychological and social support during treatment.
5. Have experienced puberty to at least Tanner stage 2 (first stage of puberty)
6. Demonstrate knowledge and understanding of the expected outcomes of HRT and sex reassignment surgery, as well as the medical and social risks and benefits of sex reassignment.

AND EITHER:

7. Your child is ≥ 16 years old and has experienced a full social transition to the desired gender for ≥ 1 year.

OR

8. Your child is 14-15 years of age, has experienced a full social transition to the desired gender for ≥ 2 years and has been on a puberty blocker for ≥ 1 year.

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

1. Visits with the endocrinologist or adolescent medicine physician in our program every 3 months.
2. Suicide risk assessment performed by our social worker during each clinic visit every 3 months.
2. Laboratory testing every 3-6 months.
3. X ray of the hand (bone age) once a year if your child is still growing.
4. Bone (dexa) scan once a year: this will allow us to monitor your child's bone density (bone strength) during treatment, which can be altered by HRT.
5. Yearly mental health assessments and completion of questionnaires with a member of our mental health care team. This will allow us to monitor your child's psychological wellbeing and adjustment while on HRT.
6. Continued counseling with a therapist during the treatment period, with the frequency recommended by the therapist.

What are the effects and risks of using these medications?

Estrogen can cause blood clots. We must be careful that your child is not at risk to develop a blood clot. Who should not take estrogen?

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 cigarettes

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 your 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 your adolescent's breasts:

- Will develop breasts.
- It takes several years for breasts to get to their full size.
- The breasts will remain, even if estrogen is stopped.
- A milky discharge from the nipples may appear. If this happens, this should be checked with your child's provider. It could be caused by the estrogen or by something else.

- While we do not know the exact risk, the risk of breast cancer may be increased to as high as if your child had been born female.

_____ 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 female shape — changing from —apple shape to —pear shape.
- Your child may lose muscle and strength in the upper body.
- The skin may become softer.

_____ I know that your adolescent's body will make less testosterone. This may affect sex life in different ways and the future ability to cause a pregnancy:

- 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 cause a pregnancy while taking hormones and may be a permanent change even hormone therapy is discontinued.
- There is a risk your child will never produce mature sperm again and this risk is further increased if your child took puberty suppressing hormones (“puberty blockers”), prior to starting feminizing medications.
- However, it is also possible that the sperm could still mature even while taking hormones. So, I know that my adolescent may get someone pregnant.
- The options for sperm banking have been explained.

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

- If present, the hair of the beard and moustache may grow more slowly than before. It may become less noticeable, but it will not go away.
- If your child went through a “male puberty” and have a “male voice”, the pitch of the voice will not rise, and the speech patterns will not become more like a woman's.
- If present, the “Adam's apple” will not shrink.
- Although these medicines can't make these changes happen, there are other treatments that may be helpful.

_____ I know that there may be mood changes with these medicines. I agree to have my adolescent continue therapy with a qualified therapist.

_____ 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 your child's health care provider and the best information that is currently available in the medical literature.

Risks of Feminizing Medications

_____ I know that the side effects and safety of these medicines are not completely known. There may be long-term risks that are not yet known.

_____ I realize that this treatment may not be able to completely prevent serious psychiatric events such as a suicidal attempt.

_____ I know that my child should not take more medicine than prescribed. Taking too much medication:

- Will increase health risks
- Won't make changes happen more quickly or more significantly

_____ I know these medicines may damage the liver and may lead to liver disease. Therefore, I should be checked for possible liver damage as long as I take them.

_____ I know these medicines cause changes that other people will notice. Some transgender people have experienced discrimination because of this. I know my child's clinician can help me find advocacy and support resources.

Risks of Estrogen

_____ I know that taking estrogen increases the risk of blood clots or problems with blood vessels which are rare in young people but that can result in:

- Chronic problems with veins in the legs
- Heart attack
- Pulmonary embolism – blood clot to the lungs – which may cause permanent lung damage or death
- Stroke, which may cause permanent brain damage or death

_____ I know that the risk of blood clots is much worse if your child smokes cigarettes.

- The danger is so high that your child should stop smoking completely if estrogen is started.

_____ I know taking estrogen can increase the deposits of fat around internal organs. This can increase the risk for diabetes and heart disease.

_____ I know taking estrogen can raise blood pressure.

_____ I know that taking estrogen increases the risk of getting gallstones, and I should talk our child's clinician if severe or long-lasting pain in the abdomen occurs.

_____ I know that estrogen can cause nausea and vomiting, and I should talk with our child's clinician if long-lasting nausea or vomiting occurs.

_____ I know that estrogen can cause migraines or make them worse if your child already has them.

_____ I know 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, headaches that are worse when waking up in the morning, and milky discharge from the nipples, these can be signs of a prolactinoma, and I should talk to my child's provider. There is a blood test that can check for this.

Risks of Androgen Antagonists

_____ I know that spironolactone affects the balance of water and salts in the kidneys. This may:

- Increase the amount of urine produced, making it necessary to urinate more frequently.
- Increase thirst.
- Increase risk of dehydration (not having enough water), and your child should make sure to drink plenty of water in hot weather.
- Rarely, cause high levels of potassium in the blood, which can cause changes in heart rhythms that may be life threatening. Your child's doctor will perform a blood test to monitor this risk while on the medication.
- Reduce blood pressure.

Requirements for HRT at the GENECIS program:

_____ 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 drug 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 drug therapy.

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

_____ I know that after my child turns 21, medical care will have to be transitioned to an adult endocrinologist.

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 him/herself 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 with the pediatric endocrinologist or adolescent medicine every 3 months, laboratory and imaging tests.

_____ I agree to have my child on continued psychological therapy or counseling with the frequency recommended by his therapist.

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 the known effects and risks. I also know that there may be unknown long-term effects of risks.
- I have had enough 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 this agreement.
- All of my questions have been answered to my satisfaction.
- I believe I know enough to give informed consent to take, refuse, or postpone therapy for my adolescent child with feminizing medications.

Based on all this information:

_____ I want my adolescent child to begin taking estrogen.

_____ I want my adolescent child to begin taking androgen antagonists (e.g., spironolactone).

_____ I do not wish my adolescent child to begin taking feminizing medication at this time.

Parent or legal guardian's name

Parent or legal guardian's signature

Date

Parent or legal guardian's name

Parent or legal guardian's signature

Date

Prescribing clinician's name

Prescribing clinician's signature

Date

ASSENT OF A MINOR:

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

Minor's Name (printed)

Minor's Signature

Date