Before using testosterone to transition and masculinize your adolescent’s body, you need to be aware the possible advantages, disadvantages and risks. We have listed them here for you. It's important that you understand all of this information before you agree to having your adolescent begin taking testosterone.

Once your questions or concerns are addressed, and you have decided to proceed with the testosterone treatment, 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 is testosterone and why is it used in people with gender dysphoria?**

Part of transition for many transgender people involves taking hormones, this is also called hormone replacement therapy or HRT. HRT in transgender males means taking testosterone. This is the sex hormone that makes certain features appear typically male. It builds muscle and causes the development of facial hair and a deeper voice.

Use of these testosterone 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”.

**Alternatives**

There are alternatives to using HRT to help people appear more male. 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.

**How is testosterone taken?**

It is usually injected every one to four weeks. It is not used as a pill because the body may not absorb it properly and may cause potentially fatal liver problems. Some people use skin creams and patches, but they tend to be more expensive and aren’t recommended for initiating puberty or for use in teenagers and young adults.
The doses used for injection differ from product to product and from patient to patient. They may range from 50 to 400mg. The injections are given in the muscle (intramuscular). It can also be given with a smaller needle under the skin (subcutaneous), this method is also effective in practice although it is considered “off label”. Your child may experience unwanted swings in hormone levels. They swings might be affected by how often the dose is given and how much of a dose is given.

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 or mental health effects.

Both testosterone, as well as the process of transitioning can affect your child’s mood. While trans men are usually relieved and happy with the changes that occur, it is important you’re 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.

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.
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.

9. 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.

   3. Laboratory testing every 3-6 months.

   4. X ray of the hand (bone age) once a year if your child is still growing.

   5. 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.

   6. 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.

   7. Continued counseling with a therapist during the treatment period, with the frequency recommended by the therapist.
Effects of testosterone

**Warning — Who should not take testosterone?**

It should *not* be used by anyone who is pregnant or has uncontrolled coronary artery disease as it could increase your risk for a fatal heart attack:

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

- Has acne
- Has a family history of heart disease or breast cancer
- Has had a blood clot
- Has high levels of cholesterol
- Has liver disease
- Has a high red-blood-cell count
- Is obese
- Smokes cigarettes

Periodic blood tests to check on the effects of the hormone will be needed. Routine breast exams and pelvic exams with Pap tests should be continued, when applicable.

**Summary of Testosterone Benefits and Risks**

<table>
<thead>
<tr>
<th>BENEFITS</th>
<th>RISKS</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Appearing more like a man</td>
<td>- Acne (may permanently scar)</td>
</tr>
<tr>
<td>o Bigger clitoris</td>
<td>- Blood clots (thrombophlebitis), risk</td>
</tr>
<tr>
<td>o Coarser skin</td>
<td>significantly increased by smoking</td>
</tr>
<tr>
<td>o Lower voice</td>
<td>- Emotional changes, for example,</td>
</tr>
<tr>
<td>o More body hair</td>
<td>more aggression</td>
</tr>
<tr>
<td>o More facial hair</td>
<td>- Headache</td>
</tr>
<tr>
<td>o More muscle mass</td>
<td>- High blood pressure (hypertension)</td>
</tr>
<tr>
<td>o More strength</td>
<td>- Increased red-blood-cell count</td>
</tr>
<tr>
<td>o No more menstrual periods</td>
<td>- Infertility</td>
</tr>
<tr>
<td>- More physical energy</td>
<td>- Inflamed liver</td>
</tr>
<tr>
<td>- More sex drive</td>
<td>- Interaction with drugs for diabetes</td>
</tr>
<tr>
<td>- Protection against bone thinning</td>
<td>and blood thinning — for example</td>
</tr>
<tr>
<td>(osteoporosis)</td>
<td>Coumadin and Warfarin</td>
</tr>
<tr>
<td></td>
<td>- Male pattern baldness</td>
</tr>
</tbody>
</table>
Please initial each statement on this form to show that you understand the benefits, risks, and changes that may occur from taking testosterone.

**Masculinizing Effects**

_____ _____ I know that testosterone may be prescribed to make your adolescent appear less like a female and more like a male.

_____ _____ 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 the changes may not be complete for two to five years after started.

_____ _____ I know that the following changes are likely and permanent even if testosterone is discontinued:

- Bigger clitoris — typically about half an inch to a little more than an inch
- Deeper voice
- Gradual growth of moustache and beard
- Hair loss at the temples and crown of the head — possibility of being completely bald
- More, thicker, and coarser hairs on abdomen, arms, back, chest, and legs

_____ _____ I know that the following changes are usually not permanent — they are likely to go away if I stop taking testosterone:

- Acne (although there may be permanent scars)
- Menstrual periods (if present), typically stop one to six months after starting
- More abdominal fat — redistributed to a male shape: decreased on buttocks, hips, and thighs; increased in abdomen – changing from “pear shape” to “apple shape”
- More muscle mass and strength
- More sexual interest
- Vaginal dryness

- More abdominal fat — redistributed to a male shape
- More risk of heart disease
- Swelling of hands, feet, and legs
- Weight gain
I know that the effects of testosterone on fertility are unknown. I have been told that your child may or may not be able to get pregnant even if testosterone is discontinued. I know that your child may still get pregnant even after testosterone stops menstrual periods.

I know that some aspects of the body will not be changed:

- Losing some fat may make breasts appear slightly smaller (if present), but they will not shrink very much.
- The voice will deepen, but other aspects of the way your adolescent speaks may not sound more masculine.
- Although testosterone 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 child continue therapy with a qualified therapist.

I know that using testosterone is an off-label use in this population. 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 Testosterone**

I know the medical effects and the safety of testosterone 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 your child should not take more testosterone than prescribed. Taking too much:

- Will increase health risks
- Won’t make changes happen more quickly or more significantly
- Can cause the body to convert extra testosterone into estrogen, and that can slow down or stop my appearing more masculine
I know that testosterone can cause changes that increase the risk of heart disease in adulthood. These changes include having:

- Less good cholesterol (HDL) that may protect against heart disease and more bad cholesterol (LDL) that may increase the risk of heart disease
- Higher blood pressure
- More deposits of fat around the internal organs

I know testosterone can damage the liver and possibly lead to liver disease and your child should be checked for possible liver damage while taking testosterone.

I know testosterone can increase red blood cells and hemoglobin. This increase is usually only to what is normal for a man and shouldn’t cause any health risks. However, there is a small possibility that higher levels of red blood cells and hemoglobin may increase my risk of life-threatening problems such as stroke or heart attack. That’s why I know your child will need periodic blood checks while testosterone.

I know that taking testosterone can increase the risk for diabetes. It may decrease the body’s response to insulin, cause weight gain, and increase deposits of fat around internal organs. Therefore, your child should have periodic checks of my blood glucose while taking testosterone.

I know that testosterone can give headaches or migraines. I know that it’s best to talk with your child’s clinician if migraines occur often or if the pain is unusually severe.

I know that testosterone can cause emotional changes. For example, your child could become more irritable, frustrated, more aggressive or angry.

I know that testosterone causes changes that other people will notice. Some transgender people have experienced harassment, discrimination, and violence because of this.

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.

**PARENTAL CONSENT:**

Our signatures below confirm that:

- My clinician has talked with me about:
  - The benefits and risks of taking testosterone
  - 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 testosterone therapy for my child.
Based on all this information:

_____ _____ I want my adolescent to begin taking testosterone.

_____ _____ I do not wish my adolescent to begin taking testosterone 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 testosterone with my parent(s) or legal guardian(s), and I wish to receive it.

__________________________________________________
Minor’s Name (printed)

__________________________________________________   _____________
Minor’s Signature                                      Date