Informed Consent for Gender Affirming Medical Care

There are different medications that can help to change your body to be more congruent with your gender.

Estrogen (estradiol) and progesterone, hormones produced in larger quantities by ovaries, can help your body become softer and curvier. There are also medications that can help you appear less firm and square. They are called androgen antagonists or anti-androgens or androgen/ testosterone blockers. Testosterone is an androgen.

Every medication has risks, benefits, and side effects that are important to understand before starting. Most medications need to be taken continuously to maintain their effects. Before using them, there are important things you need to know. These are the *possible advantages, disadvantages, risks, and warning signs*. We have listed them here for you. It's important that you understand all of this information before you start. We are happy to answer any questions you have.

Warning — who should not take estrogen?

- It should used WITH EXTREME CAUTION and clear consent of the life-threatening risk by anyone who has a history of:
    - an estrogen-dependent cancer
    - blood clots in legs or the lungs

- It should be used with caution by anyone who:
    - has a strong family history of breast cancer or other cancers that grow quicker when estrogens are present
    - has diabetes
    - has heart disease, heart valve problems, or a tendency to have easily clotted blood
    - has hepatitis
    - has high cholesterol
    - has kidney or liver disease
    - has migraines or seizures
    - has obesity
    - has a tobacco/nicotine use disorder (smokes cigarettes or vapes)

BENEFITS	RISKS
-appearing curvier -softer skin -thinning of body hair -breast growth* -fat redistribution -emotional changes — for example, larger range of emotions	-blood clots (thrombophlebitis) -sterility+ -loss of muscle mass -inflamed liver -interaction with drugs for diabetes and blood thinning — for example Coumadin and Warfarin -weight gain **These are permanent changes.* *+This may be permanent.*

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

Gender Affirming Medications:

_____ I know that estrogen and/or anti-androgens may be prescribed to help my body feel and appear softer and curvier.

_____ I know it can take many months and years 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 3-5 years after I start.

_____ I know that if I am taking estrogen I will probably develop breasts.

- I know it can take several years for breasts to get to their full size.
- I know breast development is permanent, even if I stop taking estrogen.
- I know I should examine my breasts as soon as they start growing. I should also have a clinician examine them every year. This should be done at your primary care doctor.
- I know I might have a milky discharge from my nipples — galactorrhea. If I do, I know I should check it out with my clinician because it could be caused by the estrogen or by something else.
- I know that no one knows if taking estrogen increases the risk of breast cancer.

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

  - body hair will become less noticeable and will grow more slowly. But it won't stop completely, even if I take the medicines for years.

- I will probably have less fat on my abdomen and more on my buttocks, hips, and thighs.
- fat will be redistributed to a curvier shape, changing from “apple” shape to “pear “shape
- male pattern baldness it may slow down, but probably not stop completely and hair that has been lost will likely not grow back.
- I may lose muscle and strength in my upper body.
- my skin may become softer.

_____ I know that my body will make less testosterone. This may affect my sex life in different ways and my future ability to have a biologic baby.

- I know my sperm may no longer mature and this could make me less able to cause a pregnancy. I also know I might never produce mature sperm again.
- I know that it’s also possible that my sperm could still mature, so I might get someone pregnant if we have vaginal intercourse and we don’t use birth control.
- The options for sperm banking have been explained to me. I understand that if I want the possibility of having a biological child then I should do sperm banking before starting estrogen.
- I know that my testicles may shrink down to half their size. Even so, I know that I will need regular checkups for them.
- I know that I won’t have as much semen (cum) when I come/ climax.
- I know it is likely that I won’t be hard in the morning as often as before. And it is likely that I will have fewer spontaneous erections.
- I know I may not be able to have erections hard enough for penetrative sex.
- I know that I may have less sex drive.
- I know this treatment may possibly make me permanently unable to make someone pregnant.

_____ I know that some parts of my body will *not change* much by using these medicines:

- I know that facial hair (beard and moustache) may grow more slowly than before, may become less noticeable, but it will not go away.
- I know the pitch of my voice will not rise and my speech patterns will not change due to the hormone.
- I know my Adam’s apple will not shrink.

Although these medicines can’t make these changes happen, there are other treatments that may be helpful. (for example- speech therapy, electrolysis to remove hair, surgery to shave down the Adam’s apple)

<u>Risks of Gender Affirming Medical Care</u>

_____ 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 know not to take more medicine than I am prescribed. I know it increases health risks.

_____I know that taking more than I am prescribed *won't make changes happen more quickly or more significantly.*

_____ I know these medicines cause changes that other people will notice. Some transgender people have experienced harassment, discrimination, and violence because of this. Others have lost the support of loved ones.

_____I understand that it may be in my own interest to work with a therapist that can help me through my transition.

Risks of Estrogen

_____ I know that taking estrogen increases the risk of blood clots that could result in some of the following conditions:

- chronic problems with veins in the legs
- heart attack, cancer
- 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 there is a serious risk of blood clots:

- The risk is much worse if I smoke cigarettes, especially if I am over 40.
- The danger is so high that I should stop smoking completely if I start taking estrogen.
- I know that I can ask my clinician for advice about how to stop smoking.
- Warning signs of clots include, but are not limited to: leg swelling, calf pain, shortness of breath.
- My clinician has explained to me that transdermal estrogen is considered less likely to cause blood clots compared to oral estrogen.
- We have discussed the risks and benefits of different ways to take estrogen.

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

_____ I know taking estrogen can raise my blood pressure. I know that if it goes up, my clinician can work with me to try to control it with diet, lifestyle changes, and/or medication.

_____ I know that taking estrogen increases my risk of getting gallstones. I know I should talk with my clinician if I get severe or long-lasting pain in my abdomen, especially associated with eating.

_____ I know that estrogen can cause headaches or migraines. I know I should talk with my clinician if I have headaches or migraines often or if the pain is unusually severe.

_____ 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. I understand this needs to be checked for at least 3 years after I start taking estrogen.

_____ I know that I am more likely to have dangerous side effects if:

- I smoke.
- I am overweight.
- I am over 40 years old.
- I have a history of blood clots.
- I have a history of high blood pressure.
- My family has a history of breast cancer.

<u>Risks of Androgen Antagonists</u>

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

- Increase the amount of urine I produce, making it necessary to urinate more frequently.
- Increase thirst.
- Rarely, cause high levels of potassium in the blood, which can cause changes in heart rhythms that may be life-threatening.
- Reduce blood pressure.

_____ I know some androgen antagonists make it more difficult to evaluate test results for cancer of the prostate. This can make it more difficult to check on prostate problems. I understand that if I am over 50, I should have my prostate evaluated every year.

____ I know that bicalutamide carries a risk of death associated with liver failure.

<u>Risks of Progesterone</u>

_____ I know that research on progesterone's long-term effects are limited. Progesterone may increase my risk of gallbladder disease and breast cancer.

Prevention of Medical Complications

_____ I agree to take gender affirming medications as prescribed. And I agree and to tell my care provider if I have any problems or am unhappy with the treatment.

_____ I know that the dose and type of medication that's prescribed for me may not be the same as someone else's.

_____ I know I need periodic physical exams and blood tests to check for any side effects.

_____ I know that gender affirming medications can interact with other drugs and medicines. These include alcohol, diet supplements, herbs, other hormones, and street drugs. This kind of interaction can cause complications. I know that I need to prevent complications because they can be life-threatening. That's why I need to be honest with my clinician about whatever else I take, including recreational drugs. I also know that I will continue to be provided medical care here no matter what I share about what I take.

_____ I know that it can be risky for anyone with certain conditions to take these medicines. I agree to be evaluated if my clinician thinks I may have one of them. Then we will decide together if it's a good idea for me to start or continue using them. We will engage in "shared decision making" at every step.

_____ I understand that I may be asked to stop taking estrogen before a major surgery or when I may be immobile for a long time. This will lower the risk of getting blood clots. I know I can start taking it again a week after I'm back to normal or when my clinician says it's okay. I will seek guidance from my surgeon.

_____ I understand that using estrogen in a person who is assigned male at birth is an off-label use - this means it is not approved by the government or FDA. I know that the medicine and dose that is recommended for me is based on the judgment and experience of the clinician.

_____ I know that I can choose to stop taking these medicines at any time. I know that if I decide to do that, I should do it with the help of my clinician. This will help me make sure there are no negative reactions. I also know my clinician may suggest that I cut the dose or stop taking it at all if certain conditions develop. This may happen if the side effects are severe or there are health risks that can't be controlled.



Alternatives

There are alternatives to using gender affirming medicines to help people appear softer and curvier. As a gender expansive or transgender person, I understand that aligning my body with my gender identity is not a "one size fits all" process. There are many different options and degrees of transition. If I am uncertain about what to do or how far I want to proceed with a medical transition, I will talk to my clinician about my options.

My signature below confirms that my clinician has talked with me about:

- o the benefits and risks of taking gender affirming medication
- o the possible or likely consequences of hormone therapy
- o 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 my clinician.
- 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 with gender affirming medications.

_____I am 18 years old or older.

_____ I am under 18 and my legal guardian is supportive of my decision.

Based on all this information:

_____ I want to begin taking estrogen.

_____ I want to begin taking progesterone.

_____ I want to begin taking androgen antagonists (e.g., spironolactone, finasteride, bicalutamide).

_____ I do not wish to begin taking estrogen or progesterone at this time.

_____ I do not want to begin taking androgen antagonists.

_____ _____

Patient signature Date

_____ _____

Patient printed name Date



_____ _____

Patient legal name/health insurance name Date

_____ _____

Guardian signature Date

_____ _____

Guardian signature Date