

Informed Consent

ESTROGEN and TESTOSTERONE BLOCKERS FOR TRANS CLIENTS

What is informed consent?

Before starting hormone treatment, it is important to understand the possible benefits, risks, warning signs, and alternatives. You and your healthcare provider will work together to make sure you have all the information you need to decide if hormone treatment is right for you. Agreeing to start hormone treatment once you know all of the benefits, risks, warning signs, and alternatives, and have had all of your questions answered, is called informed consent.

What are the different medications that can feminize my appearance?

Part of transition for many trans and gender nonconforming people involves taking hormones. Most people who were assigned male at birth take not only estrogens (feminizing hormones), but also androgen blockers to prevent their body from producing or utilizing testosterone (masculinizing hormones). You may want to take these medications to feminize your body, to appear more androgynous, or to feel more comfortable in your lived gender.

What is estrogen and how is it taken?

Different forms of the hormone estrogen are used to change your appearance and how you feel. Estrogen can be given as a patch (which is changed once or twice a week), an injection (weekly or every other week), or as a pill (daily or twice a day).

What are androgen blockers and how are they taken?

Medications that block the production or effects of testosterone are called androgen blockers. Androgen is another term for masculine sex hormones like testosterone.

Spironolactone is the androgen blocker that is most commonly used in the US. It is a pill that you swallow once or twice a day. Other medicines are sometimes used, but because spironolactone is relatively safe, inexpensive, and effective, it is the primary androgen blocker.

Benefits, Risks, Warnings and Alternatives

Benefits (* means it is a permanent change)

Physical changes including:

- softer skin
- slower growth of body hair
- slowed hair loss on head
- change in body fat shape: more on hips, less on belly
- breast development*
- decreased muscle mass
- decreased spontaneous erections
- smaller testicles*

Risks

- blood clots including thrombophlebitis or pulmonary embolus (blood clot in the lung)
- more risk of stroke
- emotional changes
- headache
- high blood pressure (hypertension)
- infertility
- inflamed liver
- interaction with drugs for diabetes and blood thinning — for example warfarin
- more risk of diabetes or cholesterol change
- more risk of heart disease
- less sex drive and spontaneous erection
- unknown risk of breast cancer and possible interference in assessing for prostate cancer
- risk of disturbance to body's potassium leading to dizziness or heart rhythm abnormality (spironolactone)

Warning: 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 (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

Alternatives

Not all trans and gender diverse people choose to take hormones. It is up to you whether or not you want to take them, and it will not affect how you are treated at this clinic.

There are alternatives to using feminizing medications to help people change their physical gender presentation. If you are interested in alternatives to hormone treatment, talk to your clinician about your options.

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

Informed Consent: Physical Changes

Physical Changes

_____ Estrogen or anti-androgens – or both – may be prescribed to cause changes in my appearance that are typically considered feminine.

_____ It can take several months or longer for the effects to become noticeable. No one can predict how fast or how much change will happen.

_____ If I am taking estrogen, I will develop breasts.

- It takes several years for breasts to get to their full size.
- The breasts will remain even if I stop taking estrogen.
- I might have a milky discharge from my nipples — galactorrhea. If I do, I know I should inform my clinician because it could be caused by the estrogen or by something else.
- While we do not know the exact risk, my risk of breast cancer may be increased to as high as if I had been born female
- I should take care of my breasts. This includes regular mammograms after a certain age.

_____ The following changes are usually not permanent — 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 — changing from apple shape to pear shape.
- If I have the predisposition to have male pattern baldness it may start later than it would have, but may not stop completely.
- If I stop taking hormones I may lose my hair faster than if I hadn't taken hormones.
- I may lose muscle and strength in my upper body
- My skin may become softer.

_____ My body will make less testosterone. This may affect my sex life in different ways and future ability to cause a pregnancy:

- My sperm may no longer get to mature. This could make me less able to cause a pregnancy. There is a small risk that I might never produce mature sperm again. It's also possible that my sperm could still mature even while I am taking hormones. I might get someone pregnant if we have vaginal intercourse and we don't use birth control.
- Options for sperm banking have been explained to me.
- My testicles may shrink down to half their size. They are still part of my body and I need to take care of them unless I have surgery to remove them. I will ask my clinician for an exam if I have a concern.
- I won't have as much semen when I ejaculate.
- 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 may not be able to get hard enough for penetrative sex.
- I may want to masturbate or have sex less and may find it harder to orgasm when I do. I can discuss these issues with my clinician at any time.
- I know this treatment may (but is not assured to) make me permanently unable to make someone pregnant.

_____ Some parts of my body will not change much by using these medicines.

- I know the hair of my beard and mustache may grow more slowly than before. It may become less noticeable, but it will not go away unless I have treatments like electrolysis.
- I know the pitch of my voice will not rise, and my speech patterns will not change.
- 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.

_____ There may be mood changes with these medicines. My care providers will check in regularly about how my mood is. I know there are mental health resources available to me if I need them.

Informed Consent: Risks

Risks of Estrogens and Androgen-Blocking Medications

_____ 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. This increases health risks. Taking more than I am prescribed won't make changes happen more quickly or more significantly.

_____ These medicines may damage the liver and may lead to liver disease. I will require regular blood tests for possible liver damage as long as I take them.

_____ These medicines cause changes that other people will notice. Some trans and gender nonconforming people have experienced discrimination because of this. My clinician can help me find advocacy and support resources.

Risks of Estrogen

_____ Taking estrogen increases the risk of blood clots or problems with blood vessels 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

_____ The risk of blood clots is much worse if I smoke cigarettes. 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.

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

_____ Taking estrogen can raise my blood pressure. If it goes up, my clinician can work with me to try to control it with diet, lifestyle changes, and/or medication.

_____ Taking estrogen increases my risk of getting gallstones. I should talk with my clinician if I get severe or long-lasting pain in my abdomen.

_____ Estrogen can cause nausea and vomiting. I should talk with my clinician if I have long-lasting nausea or vomiting.

_____ Estrogen can cause migraines or make them worse if I already have them. I should talk with my clinician if I have headaches or migraines often or if the pain is unusually severe.

_____ It is not yet known if taking estrogen increases the risk of prolactinomas. These are non-cancerous tumors of the pituitary gland. They are not usually life threatening, but they can damage vision and cause headaches if they are not treated properly. Changes in vision, headaches that are worse when I wake up in the morning, and milky discharge from my nipples can be signs of a prolactinoma, and I should talk to my health care provider if I develop these symptoms. There is a blood test that can check for this if I have symptoms.

_____ I am more likely to have dangerous side effects if

- I smoke.
- I am overweight.
- I have a personal or family history of blood clots.
- I have a personal or family history of heart disease and stroke.
- My family has a history of breast cancer.

Risks of Androgen Antagonists

_____ 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.

_____ Some androgen antagonists make it more difficult to evaluate test results for cancer of the prostate. This can make it more difficult to check up on prostate problems. If I have new urinary symptoms like urinating more often or difficulty urinating, I should talk with my clinician. Even if I have genital reassignment surgery the prostate is not usually removed.

Informed Consent: Prevention

Prevention of Medical Complications

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

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

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

_____ These medications can interact with other drugs and prescribed and over the counter medicines. These include alcohol, diet supplements, herbs, other hormones, and street drugs. This kind of interaction can cause complications. That's why I need to keep my clinician informed about whatever else I take. I also know that I will continue to get medical care here no matter what I share about what I take.

_____ Even if I have to stop my estrogen, I may still be able to take the testosterone blockers that I am on to help prevent the effects of my body producing testosterone again.

_____ Using these medicines to feminize is an off-label use. This means that using these medicines for feminizing therapy is not approved by the FDA. I know that the medicine and dose that is recommended for me is based on the judgment and experience of my health care provider and current guidelines for transgender care.

_____ I can choose to stop taking these medicines at any time. If I decide to do that, I should inform my clinician.

_____ My clinician may suggest that I reduce my dose or stop taking estrogens or blockers 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.

Informed Consent: Alternatives

_____ Not all trans and gender diverse people choose to take hormones and my decision about whether to take them or not will not affect how I am treated at this clinic.

_____ There are alternatives to using feminizing medicines to help people change their physical gender. Some trans and gender diverse people choose to not take hormones or have surgery and may only socially transition. If I am interested in alternatives, I can talk with my health care provider about my options.

Signature

My signature below confirms that

My clinician has talked with me about

- the physical changes and risks of taking feminizing medication;
- warnings and prevention of medical complications; and
- potential alternative treatments

I understand the risks that may be involved.

I know the information in this form includes the known effects and risks.

I understand that there may be unknown long-term effects and risks.

I understand that counseling can be beneficial for some people who are considering hormone therapy (support through the decision-making process, support with coming out, adjusting to the physical and emotional changes that may come with hormone therapy, etc.) and my provider has let me know about counseling and support options that are available to me.

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 information to give informed consent to take, refuse, or postpone therapy with feminizing medications.

Based on all this information:

_____ I want to begin taking estrogen

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

_____ I do not wish to begin taking feminizing medication at this time

Client Signature _____

Date: _____

Prescribing Clinician Signature _____

Date: _____