

CONSENT TO PERFORM HEALTH CARE PROCEDURES AND RELATED SERVICES

I. I authorize ______, my health care provider, and/or such other University of Utah Health employees and trainees my provider designates, to perform or participate in the following health care procedures and any other medical treatment necessary for my well-being and safety as described: the administration of a gonadotropin releasing hormone agent ("puberty blocker") to stop the production of sex hormones until the medication is no longer effective.

Check if name of provider supplying consent information is the same as above.

Print name of provider providing information if different from above:

(Required if different from above)

II. My provider has explained the nature of my medical condition and the nature and purpose of the health care procedures or treatments he/she is proposing. My provider has also explained alternative methods of treatment, the risks of those treatments, and what could happen if I do not receive any treatment. I have been able to ask questions about the health care procedures and the alternatives to treatment. My provider has answered my questions. I understand the risks involved and I voluntarily assume the risks in the hopes of obtaining the desired beneficial results.

III. I understand that among those who attend to patients are medical, nursing, and other health care personnel in training who may be present or provide patient care as part of their education. This is also covered in the admission conditional agreement.

Required: Signature of Patient or (Legally Authorized Person)

Required: Printed Name of Patient or (Legally Authorized Person)

(Relationship to Patient)











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Required: Printed Name of Patient or (equired: Printed Name of Patient or (Legally Authorized Person)									
((Relationship to Patient)									
Required: Provider/Staff Witnessing Signature of Patient:										
Consent obtained if by telephone: (Witness initial if yes)										
Required: Dated thisd	ay of,	20	Required: Time:							







Place Patient Label Here





Feminizing Therapy Options

- Feminizing hormone therapy usually consists of estrogen, taken as a daily or twice daily pill, or as a weekly patch or injection, plus the addition of an anti-androgen or a GnRH agonist to block the effects of testosterone in your body
- Every person responds differently to hormone therapy, and every person will have different prescriptions based on their specific risk factors and metabolism
- Dosages for adolescents are often much lower than adult doses due to differences in body size, body composition, and metabolism
- Estrogen can cause some permanent, and some reversible changes in your body, as described below

EFFECTS AND EXPECTED TIME COURSE OF A REGIMEN CONSISTING OF AN ANTI-ANDROGEN AND ESTROGEN



Years

			0	1		2		3	4		5
PHYSICAL EFFECTS	REVERSIBILITY	ONSET	$1 \rightarrow -1$	· 1		· 1	1 1	· 1 ·	· · 1 ·		Ι
Softening of skin/decreased oiliness	Reversible	3-6 months		}}}	»»»»»»»	}}}	<pre>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>></pre>	<pre>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>></pre>	//////////////////////////////////////	»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»	>>
Body fat redistribution	Reversible/Variable	3 - 6 months	s 🗾	>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>	<pre>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>></pre>	>>>>>					
Decreased muscle mass/strength ^b	Reversible	3-6 months									
Thinned/slowed growth of body/facial hair ^c	Reversible	6-12 month	is 🔰	X		>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>	»»»»»»»»»»»				
Male Pattern Baldness ^d	Reversible	1 - 3 months		>>>>>>							
Breast growth	Irreversible	3-6 months		»»»»»»	»»»»»»»»»	>>>>>					
Decreased testicular volume	Variable	3-6 months		>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>	»»»»»»»»»»	>>>>>					
Decreased libido	Variable	1-3 months		>>>>>>							
Decreased spontaneous erections	Variable	1-3 months									
Decreased sperm production	Variable	variable	>>>>>	>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>	»»»»»»»»	}}}	»»»»»»»»»»»»	»»»»»»»»»»»»	*****	»»»»»»»»»	>>
Erectile Dysfunction	Variable	variable	>>>>>	>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>	»»»»»»»»	>>>>>	````````````	»»»»»»»»»»»»		»»»»»»»»»	>>>
				Exp	ected (Onset		Expected	d Maximu	ım Effeo	ctª

Source: https://teenhealthsource.com/blog/faq-what-happens-to-your-body-on-hormones/

Contraindications: you should not use estrogen if you have a history of blood clots, have migraines with aura, or have an estrogen-dependent cancer

Use With Caution:

- Family history of estrogen-dependent cancers
- If you are smoking, are obese, or have heart disease, high cholesterol, liver or kidney disease, seizures, or diabetes

Other Considerations:

- Estrogen prescription requires a letter of support from a mental health professional
- Use of estrogen for gender-affirming hormone therapy is not FDA approved- there may be long-term risks that are currently unknown
- Because of the risks associated with estrogen use, your provider will be checking labs every 3 months for the first year of being on estrogen, and then every 6 months (on a stable dose) until adulthood
- Estrogen is associated with increased risks of high blood pressure, blood clots, heart disease, diabetes, liver and kidney disease, non-cancerous tumors of the pituitary gland, gall stones, breast cancer, headaches and migraines, and loss of fertility
- It is strongly advised not to take more medication than is prescribed to you; taking more medication than prescribed will not lead to faster or increased feminization, and will increase your risks of adverse side effects, including abnormal breast shape
- Feminizing medications will result in changes that will be noticeable to other people, and some transgender people in similar circumstances have experienced harassment, discrimination, and violence, while others have lost support of loved ones.

Progesterone

• There are no validated studies showing improved feminization with progesterone. There is anecdotal evidence of trans women who have experienced increased breast/areola development, and/or increased mood/libido with progesterone. Other people have noticed worsening effects on mood. There is no evidence that use of progesterone is harmful in transgender therapy. You can discuss with your provider if you think progesterone is a good fit for you and your journey.

Risks of Testosterone Blockade

- Use of androgen blockers and GnRH agonists for gender-affirming hormone therapy is not FDA approved- there may be long-term risks with use that are not currently known
- Androgen blockers and GnRH agonists do not require a letter of support from a therapist, **Risks of Spironolactone**
- Increased urination, possible changes in kidney function, drops in blood pressure, lightheadedness, increased thirst
- Increase in the potassium in your blood, which can lead to muscle weakness, nerve problem, and dangerous heart arrhythmias
- Irreversible breast growth

Risks of Bicalutamide

- Increased risk of liver damage, which requires monitoring with lab work
- Irreversible breast growth

Consent Form: Feminizing medication for transgender clients

In order to feminize your body, you may want to take estrogen and other medications.

What are the different types of medications used for feminization?

Estrogen is the primary medication used for feminization, and it comes in different types

(injectable, oral, topical). Estrogen is the primary sex hormone produced by people with ovaries.

You will talk with your provider about which dose and type is best for you and your certain

medical needs.

Androgen antagonists/anti-androgens/androgen blockers are another type of medication that

can help you appear less masculine. Androgens are the primary sex hormone produced by

people with testicles.

Warning- who should not take estrogen?

Estrogen should not be used by people with a history of an estrogen-dependent cancer or

people with a history of blood clots in the deep veins.

Estrogen should also be used with caution and only after fully discussing the risks in people who

- Have a strong family history of cancers that grow quicker when estrogens are present
- Have diabetes
- Have eye problems such as retinopathy
- Have heart disease, heart valve problems, or a tendency for their blood to easily clot
- Have hepatitis
- Have high cholesterol
- Have kidney or liver disease
- Have migraines or seizures
- Is obese
- Use nicotine (especially smoking)

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

_____ I know that estrogen, anti-androgens, or both may be prescribed to help me appear less masculine and more feminine

_____ I know that it can take several months to several years for effects to become noticeable, and no one can predict how much my body will change

_____ I know that some changes are permanent, and will not go away even if I stop taking hormone therapy

_____ I know that some parts of my body will not change. Hormone therapy will not change the bony structure of the face, the Adam's apple will not shrink, the pitch of your voice will not change.

____ I know that if I am taking estrogen, I will likely have breast/chest growth that is permanent

- It may take several years to reach maximum growth
- Breast/chest growth will be permanent, even if I stop taking estrogen
- I should examine my breast/chest as soon at there is growth, and should have a clinician examine them according to current recommendations
- I might have milky discharge from my nipples (galactorrhea). If I do, I know I should check with my provider to make sure it is not caused by something dangerous
- There are no data on whether or not estrogen increases the risk of breast cancer

_____ I will experience changes to my body hair and hair growth patterns will likely go away if I stop taking my medications

- My body and facial hair will become less noticeable and will grow more slowly. It will not stop or go away completely, even after being on medications for many years
- If I have thinning at my temples and the top of my head, the hair loss may slow down, but will probably not stop completely. The hair I have lost will likely not grow back.

_____ I know that if I am taking estrogen, I will likely experience changes in how fat is distributed on my body, and will experience a loss of muscle mass. These changes are not permanent, and will go away once I stop taking estrogen

- Skin may be softer
- Muscle mass decreases, and I may notice a loss of upper body strength
- Fat will redistribute to my hips/butt/thighs

I know if I am taking estrogen, I will experience sexual side effects. Some of these effects

may be permanent, and others may or may not be permanent.

- My testicles may shrink 25-50%. They should still be examined as per healthcare guidelines. This may be permanent.
- It may be harder to orgasm, and there may be less cum if I do orgasm
- It may be more difficult to have erections, and my erection may be too soft to engage in penetrative sex. If this ability is important to you, please talk with your provider about possible solutions.
- There may be a decrease in morning and spontaneous erections
- My sperm may not mature, and I may become unable to cause a pregnancy. This ability may or may not return after stopping hormone therapy. I have talked to my provider about sperm banking if desired.
- It is also still possible that I may be able to cause a pregnancy, so birth control is still necessary for sex with someone with a uterus and ovaries.
- I may not be as interested in having sex

I may experience emotions differently while taking estrogen. This will likely reverse if

hormone therapy is stopped.

- I may have increased emotional responses while taking estrogen
- My mental health may improve after starting hormone therapy
- I may cry more, or be able to cry more easily
- The effects of hormone therapy on the brain are not completely understood

Risk of Androgen antagonists/"testosterone blockers"

_____ I know that spironolactone affects the balance of water and salts in the kidney. This can cause

- Increased urine production, needing to urinate more frequently
- Drops in blood pressure/feeling light-headed
- Increased thirst
- Rare increases in potassium in your blood and body: this can lead to muscle weakness, nerve problems, and irregular heart rhythms

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 not yet known.

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

_____ I know these medications can cause changes that other people will notice. Some transgender and gender non-conforming people have experienced harassment, discrimination, and violence because of this. Others have lost support of loved ones. I know my clinician can help me find advocacy and support resources.

Risks of Estrogen

____ I know taking estrogen increase the risk of blood clots 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 I smoke cigarettes or vape. I know this danger is so high that I should stop smoking or vaping completely if I start taking estrogen. I know I can ask my clinician for advice on how to stop smoking or vaping.

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

____ I know that taking estrogen increase mt risk of getting gallstones. I know I should talk with my clinician if I get severe or long-lasting pain in my abdomen.

____ I know estrogen can cause nausea and vomiting. I know I should talk with my clinician if I have long-lasting nausea or vomiting.

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

_____ I know that it is not yet known if taking estrogen increase the risk of prolactinomas. These are non-cancerous tumors of the pituitary gland. I know that they are not usually life-threatening, but they can damage vision and cause headaches. I know this needs to be checked on for at least three years after I start taking estrogen.

I know 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

Prevention of Medical Complications

____ I will only take my androgen blockers and/or estrogen at the dosage and route prescribed by my medical provider

____ I will inform my medical provider of any prescription drugs, dietary supplements, herbal or homeopathic drugs, other hormones, and street drugs or alcohol that I am taking so we can discuss possible side effects and interactions they may have with my hormone therapy. I also know that I will continue to receive medical care here no matter what I share about what I take

____ I will keep my scheduled appointments, including routine blood draws to monitor for potential harmful effects and ensuring my hormone therapy is safe and effective

____ I realize that taking more than my prescribed dose of androgen blockers and/or estrogen will not increase the rate of my changes, and may increase potential side effects of the medications

_____ I know that it can be risky for anyone with certain conditions to take these medications. I agree to be evaluated if my provider thinks I may have one of them. Then we will decide if it is a good idea for me to start or continue using them.

_____ I know I should stop taking estrogen two weeks before any 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 them again in a week after I'm back to normal or when my provider says it's okay.

_____ I know using these medications for feminization is an off-label use. This means it is not approved by the government. I know that the medication and dose that is recommended for me is based on the judgement and experience of the clinician.

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

My signature below confirms that

- My clinician has talked with me about
 - o 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 know effects and risks. I also know that there may be unknown long-term effects and risks
- I have had enough time 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 (parent permission and assent if younger than 18 years) to take, refuse, or postpone therapy with feminizing medications.

Based on this information

____ I want to start taking estrogen

- ____ I want to start taking androgen antagonists (spironolactone or others)
- ____ I do not want to begin taking feminizing medications at this time

Client signature and printed name

Date

Date

Parent/guardian signature and printed name

Prescribing clinician signature

Date

EFFECTS AND EXPECTED TIME COURSE OF A REGIMEN CONSISTING OF AN ANTI-ANDROGEN AND ESTROGEN



 a) Estimates represent published and unpublished clinical observations
 b) Significantly dependent on amount of exercise c) Complete removal of male facial and body hair requires electrolysis, laser treatment, or both

d) No regrowth, loss stops

Expected Maximum Effect^a

Source: https://teenhealthsource.com/blog/faq-what-happens-to-your-body-on-hormones/

Expected Onset

Masculinizing Consent

What is testosterone? Testosterone is the sex hormone produced by the testicles. It is the hormone mainly responsible for most masculine features (increased muscle mass, development of facial hair, a deeper voice).

How is testosterone taken? It is injected every one to four weeks. It cannot be taken as a pill because it does not absorb properly. It is possible to use testosterone via a patch or a gel, but they are more difficult to use, and more expensive.

Testosterone should not be used by anyone who is pregnant, or who has uncontrolled coronary artery disease.

It should be used with **caution** in people with acne, family history of heart disease or breast cancer, with blood clots, with high levels of cholesterol, with liver disease, with a high red blood cell count, who are overweight, and who use nicotine.

Periodic blood tests are needed to check on the effects of the hormone. Routine breast/chest exams should be continued and pelvic exams with Pap smear tests should be continued for people with cervixes.

Benefits	Risks
 Bigger clitoris (permanent) Coarser skin Lower voice (permanent) More body hair (permanent) More facial hair (permanent) Increased muscle mass Increased strength Possible stopping of menses More physical energy More sex drive Protection against bone thinning 	 Acne (may scar) Blood clots Emotional changes (more aggression/irritability) Headache High blood pressure Increased red blood cell count Infertility Inflamed liver Drug interactions Male patterned baldness More abdominal fat Increased risk of heart disease Swelling of hands, feet, and legs Weight gain

EFFECTS AND EXPECTED TIME COURSE OF A REGIMEN CONSISTING OF TESTOSTERONE



					Yea	ars		
			0	1	2	3	4	5
PHYSICAL EFFECT	REVERSIBILITY	ONSET	[-1, 1, 1]	· I · ·	1 1 1	1 I I	1 I I I	I
Skin oiliness/acne	Reversible	1-6 months						
Body fat redistribution	Reversible/Variable	3 - 6 months		·>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>				
Increased muscle mass/strength ^b	Reversible	6-12 months		·/////////////////////////////////////				
Facial/body hair growth	Irreversible	3-6 months		·››››	»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»	>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>		
Scalp hair loss	Irreversible	variable		>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>	*****	»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»	»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»	>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>
Cessation of menses	Reversible	2-6 months						
Clitoral enlargement	Irreversible	3-6 months						
Vaginal atrophy	Reversible	3 - 6 months						
Deepened voice	Irreversible	3 - 12 months						
Infertility	Irreversible	variable	>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>	»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»	<pre>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>></pre>	»»»»»»»»»»»»»»»»»	<pre>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>></pre>	»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»
a) Estimates represent published and unpublished	clinical observations			Expected C	Onsetª 🚬	Expecte	d Maximu	m Effect ^a

b) Significantly dependent on amount of exercise

Source: https://teenhealthsource.com/blog/faq-what-happens-to-your-body-on-hormones/

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

I know that testosterone is prescribed to reduce feminine characteristics and masculinize a person's body.

I know that it can take several months or longer to notice the effects of testosterone. I know no one can predict how fast or how much change will happen. I know that it may take two to five years for full effects to be seen.

I know the following changes are likely permanent even if I stop taking testosterone:

- Bigger clitoris usually a half an inch to over an inch
- Deeper voice
- Facial hair growth
- Hair loss at temples and crown of the head- with the possibility of being completely bald
- More, thicker, and coarser hair on abdomen, arms, back, chest, and legs

____ I know the following changes are usually not permanent- they will likely go away if I stop taking testosterone:

- Acne (may permanently scar)
- Menstrual periods usually stop one to six months after starting, but up to 30% of people will need additional medications to stop menses
- Increased fat on the abdomen, and decreased fat on buttocks, hips, and thighs
- More muscle mass and strength
- Higher sex drive
- Vaginal dryness and loss of elasticity

I know that the effects of testosterone on fertility are unknown. I have been told that I may or may not be able to get pregnant even after stopping testosterone. I know that I can still get pregnant even if testosterone stops my periods. I know that I need to continue to use contraception if I am having sex with a partner with a penis and sperm. I know that I cannot take testosterone if I become pregnant.

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

- Losing some fat may make my breast appear smaller, but they will not shrink very much
- My voice may deepen, but other aspects of the way I speak will not necessarily sound more masculine

I know there are options for chest masculinization and vocal therapy, and I will ask for referrals if I want them

Risks of testosterone

I know that the medical effects and safety of testosterone are not completely known. There may be long-term risks that are not known.

____ I know not to take more testosterone that is prescribed to me. I know that taking more than prescribed increases risks and does not make changes happen more quickly or significantly. I know that my body can covert extra testosterone into estrogen, and that can slow down the rate of my masculinization.

I know that testosterone can cause changes that increase my risk of heart disease. These changes are:

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

____ I know that my risk of heart disease is higher if people in my family have had heart disease, if I am overweight, or if I use nicotine

I know that I should periodic heart-health checkups as long as I take testosterone. I know that means that I must watch my weight and cholesterol levels and have them checked by my clinician.

I know testosterone can be damaging to my liver and possibly lead to liver disease. I know I should be checked for liver damage as long as I am taking testosterone.

I know that testosterone can increase my red blood cells and hemoglobin. I know that the increase is usually just to what is normal for a cisgender man. I know that a higher increase can cause problems like stroke and heart attack. I know I will need periodic blood tests to monitor my red blood cells as long as I take testosterone.

I know that taking testosterone can increase my risk for diabetes. It may increase my body's response to insulin, cause weight gain, and increase deposits of fat around my internal organs. I know that I should have periodic checks of my blood glucose as long as I am taking testosterone.

____ I know my body can turn testosterone into estrogen. I know that no one know is that could increase the risk for cancers of the breast, ovaries, or uterus.

I know taking testosterone can thin the tissue of my cervix and the walls of my vagina. This can lead to tears or abrasions during vaginal sex play that can increase my risk of getting a sexually transmitted infection, including HIV. I know I should be truthful with my clinician about my sex life and learn to best ways to prevent and check for infections.

I know that testosterone can give me headaches or migraines. I know that I should talk to my clinician if I get them a lot or if the pain is unusually severe.

I know that testosterone can cause emotional changes. I might become more irritable, frustrated, or angry. I know my clinician can help me find resources to explore and cope with these changes.

I know that testosterone causes 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 know my clinician can help me find advocacy and support resources.

Prevention of Medical Complications

____ I agree to take testosterone as prescribed. And I agree 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 is prescribed to me may not be the same as someone else's.

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

I know that testosterone can interact with other drugs and medications. These include alcohol, diet supplements, herbs, other hormones, and street drugs. This kind of interaction can cause complications that can be life-threatening. I know that I need to be honest with my clinician 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.

I know that it can be risky for anyone with certain conditions to take testosterone. I agree to be evaluated if my clinician thinks I may have one of them. Then we will decide if it is a good idea for me to start or continue to take testosterone.

I know the use of testosterone for masculinization is an off-label use. I know this means it 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 the health care provider.

I know that I can choose to stop taking testosterone at any time. I know if I decide to do that, I should do it with the help of my clinician to help prevent negative reactions. I also know that my clinician may suggest that I cut the dose of stop taking it at all if certain conditions develop. This may happen if the side effects are severe or there are health risks that cannot be controlled.

Alternatives

There are alternatives to using testosterone that can help you appear more masculine. If you are interested in alternatives to testosterone therapy, talk with your clinician about your options.

My signature below confirms that

• My clinician has talked to be about the benefits and risks of testosterone, the possible and likely consequences of hormone therapy, and alternative treatment options.

- I understand that risks may be involved.
- I know that the information in this form includes known effects and risks. I also know there may be unknown long-term effects or risks.
- I have had the 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 (parent permission and assent if younger than 18 years) to take, refuse, or postpone testosterone therapy.

Based on all this information

____ I want to begin taking testosterone

I do not want to begin taking testosterone at this time

Client signature and printed name

Date

Parent/guardian signature and printed name

Date

Prescribing clinician signature

Date

Masculinizing Therapy Options

- Masculinizing hormone therapy usually consists of testosterone injections, injected either • into the muscle or subcutaneously every 7 to 14 days
- Every person responds differently to hormone therapy, and every person will have • different prescriptions based on their specific risk factors and metabolism
- Dosages for adolescents are often much lower than adult doses due to differences in body • size, body composition, and metabolism
- Testosterone can cause some permanent, and some reversible changes in your body, as • described below

EFFECTS AND EXPECTED TIME COURSE OF A REGIMEN CONSISTING OF TESTOSTERONE



					Tears	,		
			0	1	2	3	4	5
PHYSICAL EFFECT	REVERSIBILITY	ONSET	[-1, -1, -1]	$\ f_{i} \ _{L^{\infty}(\Omega)} \leq 1$		() () ($\ \ \ = \ \ $	~ 1
Skin oiliness/acne	Reversible	1-6 months		>>>				
Body fat redistribution	Reversible/Variable	3 - 6 months		·····				
Increased muscle mass/strength ^b	Reversible	6-12 months						
Facial/body hair growth	Irreversible	3-6 months		*****	»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»			
Scalp hair loss	Irreversible	variable		>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>	*****	*****	»»»»»»»»»»»»»	»»»»»»
Cessation of menses	Reversible	2-6 months						
Clitoral enlargement	Irreversible	3-6 months		>>>				
Vaginal atrophy	Reversible	3 - 6 months		»»				
Deepened voice	Irreversible	3 - 12 months						
Infertility	Irreversible	variable	>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>	»»»»»»»»»»»»»»»»»		»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»	»»»»»»»»»»»»	»»»»»»
a) Estimates represent published and unpublished	d clinical observations		— —	up a stard Or				ffe eta

a) Estimates represent published and unpublished clinical observations b) Significantly dependent on amount of exercise

Expected Onset^a Expected Maximum Effect^a

Years

Source: https://teenhealthsource.com/blog/faq-what-happens-to-your-body-on-hormones/

Risks of Masculinizing Therapy Options

Contraindications: do not use testosterone if

• You are pregnant or have uncontrolled coronary artery disease

Use With Caution:

• If you are smoking, are obese, or have heart disease, high cholesterol, liver disease, acne, high red blood cell count, blood clots, or a family history of heart disease or breast cancer

Other Considerations:

- Use of testosterone for gender-affirming hormone therapy is not FDA approved- there may be long-term risks that are currently unknown
- A letter of support from a mental health provider is required to start testosterone therapy
- Because of the risks associated with testosterone use, your provider will be checking labs every 3 months for the first year of being on testosterone, and then every 6 months (on a stable dose) until adulthood
- Testosterone is associated with increased risks of high cholesterol, increased red blood cell count, heart disease, diabetes, liver disease, headaches and migraines, emotional changes, and loss of fertility
- Testosterone can also cause thinning of the tissues in your cervix and vagina. This can lead to tearing during vaginal sex play, and can increase the risk of getting sexually transmitted infections
- It is strongly advised not to take more medication than is prescribed to you; taking more medication than prescribed will not lead to faster or increased masculinization, and will increase your risks of adverse side effects
- Your body can turn extra testosterone into estrogen, which can decrease the masculinizing effects as well as increase possible risk for breast, ovarian, and uterine cancers
- Masculinizing medications will result in changes that will be noticeable to other people, and some transgender people in similar circumstances have experienced harassment, discrimination, and violence, while others have lost support of loved ones.

Menses Suppression

- If you are interested in stopping monthly bleeding, you can start norethindrone pills. These are progestin-only pills that need to be taken at the same time every day for effective suppression of bleeding, and can be prescribed at the Adolescent Medicine Clinic.
- GnRH agonists (puberty blockers) can also be used to stop monthly bleeding, and are a great option if covered by your insurance.

Preventing Pregnancy

- If you are engaged in penetrative vaginal sex with a partner who is capable of producing sperm, you should be using some form of birth control. Testosterone does not always stop ovulation, and can cause birth defects if a pregnancy occurs.
- Hormonal IUDs and the Nexplanon are extremely effective forms of birth control. If interested, Planned Parenthood, and the Pediatric and Adolescent Gynecology Clinics are very experienced in IUD and Nexplanon insertion.

Non-binary/Gender-fluid Options

- There is no "right way" to transition, and if you are non-binary or gender-fluid, we will work with your provider to create unique plan that best fits your needs and desires. This can include hormone therapy, pausing the production of sex hormones, or stopping periods.
- Should you choose to start hormone therapy, the risks and expected effects of estrogen, anti-androgen, and testosterone therapy can be found in the handouts for feminizing and masculinizing therapy options. A relationship with a therapist and letter of support, as well as parental/guardian consent are required to start any feminizing or masculinizing hormones if you are under the age of 18.
- While doses of hormones can be adjusted to better control levels of masculinization/ feminization, it is not possible to pick and choose which hormonal effects a person's body responds to. For example- it is not possible to just obtain the voice lowering effects of testosterone without the associated body hair growth, possible mood effects, and possible scalp hair loss.

The following graph is an example of possible medications and other therapies to help achieve your transition goals, however the Adolescent Medicine Clinic can only assist with the circled options.



Source: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7356977/

Options for Testosterone Suppression

Medication	Spironolactone	Bicalutamide	GnRH agonists
How is it taken	Pill taken orally once or twice daily, in ranges from 50-200 mg	Daily 50 mg pill taken orally	Histrelin- subcutaneous implant in the arm Leuprolide acetate- injections every 3-6 months
How it works	Decreases testosterone production and its effects	Directly competes with androgens (testosterone and dihydrotestosterone) at their binding sites, and blocking their action in the body	Turns off the hypothalamic- pituitary-gonadal access, which stops the secretion of sex hormones at their source
Most common use	Most often used as a diuretic (water pill), or for hormonal acne treatment	Most often used in the treatment of prostate cancer	Most often used for puberty suppression in children with precocious puberty
Risks	Possible changes in kidney function, drops in blood pressure, light-headedness, dangerous heart arrhythmias, irreversible breast growth	Possible liver damage, breast growth, and possible lung issues	Possible decrease in bone mass
Effects	Low testosterone suppression, mild feminization	Significant testosterone suppression, mild feminization	High testosterone suppression, no feminization
Expense (from GoodRx)	\$5-20 a month, depending on frequency and dose	\$20-140 a month	\$600-3000 for leuprolide, \$6000- 8000 for histrelin

More information on GnRH agonists available on the "Puberty, sex hormones, and puberty blockers" handout

<u>Preparing for Gender Affirming Hormone Therapy and the Medical</u> <u>Management of Gender in the Adolescent Medicine Clinic</u>

- You must establish with a mental health therapist. The Adolescent Medicine Clinic conforms to the guidelines set by the Endocrine Society and the World Professional Association for Transgender Health, which recommend a letter of support for minors prior to starting hormone therapy. We require a letter of support from a licensed mental health professional before prescribing hormones to anyone under the age of 18. We encourage all patients to establish and maintain a relationship with their therapist as they receive and adjust to hormone treatment in our clinic. We do not offer mental health services in our clinic. We recommend using the find a therapist tool. Psychology Today and filtering by issue (transgender)/insurance/location/age or contacting the behavioral health benefits at your insurance provider and asking for a gender-affirming therapist referral.
- You will need to get your **labs** drawn before you start on any medications, so that the providers can have a baseline to compare to in the future. You will also need labs completed several weeks prior to follow-up visits and/or any time there have been dose adjustments typically every 3 months in the first year on hormone therapy. Your provider will order them, and you can get them done without any additional paperwork at any Intermountain clinic with laboratory facilities. If your insurance prefers you to use another lab facility, please ask for a copy of the lab order or ask the care team to email you the lab order or send it to your preferred facility.
- If you are interested in feminization, you may be able start GnRH agonists, spironolactone, or bicalutamide to block or reduce the effects of testosterone in your body. Both spironolactone and bicalutamide can cause irreversible chest growth, so while they do not require a letter of support to start, you should be very aware of the potential side effects. All medications prescribed to minors in our clinic require the consent of a parent of legal guardian.
- If you are interested in stopping monthly bleeding, you can start norethindrone pills. These are progestin-only pills that need to be taken at the same time every day for effective suppression of bleeding, and can be prescribed in the Adolescent Medicine Clinic, Adolescent Gynecology, and sometimes by a PCP. Hormonal IUDs and the Nexplanon can also stop bleeding in 30-70% of people, and are extremely effective forms of birth control. They are also progestin-only methods, and can be combined with norethindrone to suppress bleeding if the device alone does not stop the bleeding. If interested, Planned Parenthood, and the Adolescent Gynecology Clinics are very experienced in IUD and Nexplanon insertion.
- If you are wanting to stop further masculinization or feminization, a GnRH agonist (puberty blocker) may be prescribed. There are many insurances that cover these medications, but they are often expensive and require a prior authorization from your insurance. Some insurance companies require that patients be established with a mental health provider before authorizing puberty blockers. Puberty blockers are not prescribed until puberty has started and will require labs and a physical exam to determine readiness.

Puberty, sex hormones and "puberty blockers"

What is Puberty?

Puberty starts when your body begins to make sex hormones.

Sex hormones (testosterone and estrogens) are what cause the body to develop secondary sexual characteristics.

Secondary sexual characteristics include:

- In people with testicles:
 - vocal changes (e.g., voice deepening, voice cracking)
 - development of Adam's apple (thickening of thyroid cartilage)
 - increased muscle development
 - broadening of the shoulders
 - hair growth (e.g., facial, armpit, nipple and chest hair)
 - sometimes thinning or loss of scalp hair on the head

- in people with ovaries:
 - o breast tissue growth
 - Increases body fat and changes in body fat distribution
 - Widening of the hips
 - o decreases in muscle mass
 - can cause scalp hair to thicken
 - softening of the skin and body hair

Puberty usually starts when people with ovaries are between 8-13 years old and people with testes are between 9-14 years. Your doctor will perform a physical exam at your visit to determine which stage of puberty you are in.

What are puberty blockers?

Puberty blockers are GnRH agonists. These are drugs used to "pause puberty".

The brain and the gonads (testes or ovaries) speak to each other with chemical messengers. The messengers involved in puberty are gonadotropin releasing hormone (GnRH), luteinizing hormone (LH), follicle stimulating hormone (FSH), estrogen and testosterone. GnRH causes the production of LH and FSH; LH and FSH trigger the production of estrogen and testosterone. The hormone blocking effects of GnRH agonists are completely reversable. Once the puberty blocker is stopped, puberty will resume.



Why and when to start puberty blockers

Puberty can be a difficult time of transition for everyone, but if you are transgender, nonbinary, intersex, or uncertain of your gender identity, puberty can be extra challenging. Blockers can be used to "pause" puberty, giving you time to further explore gender identity before puberty causes any permanent changes. If started early enough, blockers can pave the way for patients to benefit from pubertal development in line with their gender identity without developing unwanted physical changes that could later require surgery to reverse.

Your doctor will determine if and when it is time to start a puberty blocker. Puberty blockers are not started before puberty begins. Readiness for a blocker is determined with lab work and a physical exam.

For lots of people, gender identity isn't something they question until they're well into puberty or adulthood. GnRH agonists are used to effectively stop or pause the development of secondary sex characteristics throughout puberty and to suppress androgens through adulthood; but because these medications can be quite expensive, we usually discuss other options for patients that have completed puberty.

What to expect when starting a puberty blocker

It can take 1-2 months for the blocker to start working.

If GnRH agonists are administered at the beginning of puberty, some regression of breast development is likely in birth assigned females and in birth assigned males the testes may decrease in size and the penis will stop growing.

If you are further along in puberty there will likely be no regression of breast development or reversal of any secondary sex characteristics that have already happened, but development will stop.

Are these drugs safe and what are the potential side effects of puberty blockers?

GnRH agonists have been safely used in children to suppress puberty since the 1980s. They are also prescribed for adults with cancers that are influenced by sex hormones (e.g., prostate and breast cancers). They are used to safely and effectively mitigate the unwanted effects of these hormones in a variety of conditions across the lifespan.

The use of hormone blockers is fully supported for use in achieving puberty suppression in adolescents with gender incongruence by the World Professional Association for Transgender Health (WPATH) and the Endocrine Society.

Risks associated with GnRH agonists:

Bone density:

Our bones need sex hormones to stay healthy and strong. Though bone density is affected by the use of blockers, bone mineralization is restored when sex hormones are reintroduced. Blockers can be safely used for up to 4 years, but we may need to check bone density to assess bone health when using blockers for longer periods of time.

Calcium and vitamin D are important for bone health in all adolescents, but especially important for people taking puberty blockers. We monitor risk factors affecting bone health for all patients on hormone blockers in our clinic.

Brain development:

Because we lack long-term studies related directly to the use of GnRH agonists in adolescents, we have no data on how the temporary absence of sex hormones might affect brain development.

Side effects of GnRH agonists:

Side effects are most often a result of the withdrawal of sex hormones and are usually more pronounced in patients that are in the later stages of puberty.

The following side effects of the GnRH agonists we prescribe are reported in less than 2% of patients:

- Hot flushes
- Fatigue
- Testicular atrophy
- Headaches

Frequently asked questions:

Will using a puberty blocker affect my ability to have children if I want them later in life? I've already been through puberty, am I too old for blockers? How long does it take for a blocker to start working? Will blockers stop me from getting acne? How much do blockers cost and are they covered by my insurance? Will my insurance cover blockers? What if my insurance doesn't cover blockers? Will Medicaid pay for blockers? What about co-pay cards and manufacturer discounts? Are there other ways to suppress puberty if blockers aren't an option?

Will using a puberty blocker affect my ability to have children if I want them later in life?

No. The effects of these drugs are fully reversable and there is no long-term effect on fertility related to the blockers after the blockers are stopped.

If and when you decide to use gender affirming hormones, it is important to discuss options for fertility preservation before beginning hormone therapy. For some people it is important to discuss options for fertility preservation before beginning puberty blockers.

I've already been through puberty, am I too old for blockers?

Maybe. Most of the changes that have already happened as a result of puberty will not be reversed with puberty blockers. Using a blocker will prevent further development and may still make sense for you. Because these drugs can be expensive, it may not be the best choice for you or your family if you have completed puberty. For some girls and women who have testicles, blockers may be preferred to suppress testosterone even when they are on estrogen therapy.

How long does it take for a blocker to start working?

When a blocker is first started it can take up to 1-2 months to stop the production of sex hormones. For most people this happens within the first month. Because of the way these drugs work, you may feel the effects of puberty more intensely in the first few weeks after starting a blocker.

Will blockers stop me from getting acne?

No. While acne, armpit hair and pubic hair are all associated with puberty, they are influenced by hormones produced in other parts of your body and will not stop in the absence of sex hormones.

How much do blockers cost and are they covered by my insurance?

Puberty blockers are expensive. These drugs almost always need to be filled through specialty pharmacies with a prescription. If you are using insurance, your insurance will dictate which specialty pharmacy you will need to use to fill your prescription. GnRH agonists are FDA approved for several diagnoses but are considered "off-label" for patients with gender dysphoria/ gender incongruence diagnosis.

We prescribe the following GnRH agonists to be administered in our clinics:

- Histrelin 50mg this is a subcutaneous implant that is placed in the fatty tissue on the underside of the patient's arm. Histrelin is usually effective for 18-24 months. Histrelin is placed in our office during a regular clinic visit with a numbing agent. There is a procedure fee associated with the placement of the implant in addition to the cost of the medication.
- Leuprolide acetate 22.5mg/30mg/ or 45mg these are injections that can be administered every 3/4/or 6 months (depending on dose). These injections are administered by a nurse in clinic.

Will my insurance cover blockers?

Many insurance plans cover GnRH agonists even for the diagnosis of gender dysphoria, but coverage varies from plan to plan. When speaking with your insurance you will likely be asked for a diagnosis, or ICD 10, code. The ICD 10 code for gender dysphoria is F64.0.

Most insurances will cover GnRH agonists for FDA approved uses, but because this will be prescribed off-label, it bears repeating that the medication will be used "off-label" when talking with insurance and verifying your coverage for this specific diagnosis.

Depending on your insurance plan you may need a "prior-authorization". We have a team that can help with that. Even if your insurance approves the medication, you will likely owe a co-pay to purchase the drug. Typically, insurance will pay a percentage of the cost of the medication after you have met your deductible. These drugs are billed through your medical benefit or through your pharmacy benefit. The implant is almost always billed as medical, while the injections are usually billed through pharmacy – again, this is determined by your insurance plan.

Will Medicaid pay for blockers?

There are currently 2 Utah Medicaid providers that cover puberty blockers: Select Health Community Medicaid and Healthy U Medicaid. If you have Molina or Traditional Medicaid, they do not currently cover GnRH agonists for this diagnosis (this could change in time). It is easy to switch to the Medicaid of your choice – though you can call to switch at any time, it may be months before the new coverage is in effect. We recommend you do this right away if you or your child will be receiving any gender management care and are on UT Medicaid.

What if my insurance doesn't cover blockers?

Many insurances invite you to appeal a denial with a letter of medical necessity. We can write that for you. Sometimes an insurance company will make an exception and cover the medication, often they will not. It's still worth trying if it's presented as a possibility. In the end, lots of people end up purchasing these medications without using insurance and for many people, the cash price is less than their co-pay after insurance.

All of these drugs can be purchased for a "cash-pay" price. This is almost always much less than what your insurance is billed for the same medication. This expenditure cannot be applied toward your insurance deductible because it is not processed through insurance. The prices of these drugs change frequently. As of spring 2021, cash-pay prices range from \$650/ 3-month and \$1100/ 6-month injections of LupronDepot to \$6200 for the histrelin implant.

What about co-pay cards and manufacturer discounts?

These discounts don't apply to drugs being prescribed "off-label". It is not unusual to call and ask if there are any assistance programs and be told that there is co-pay assistance available. There are even representatives at these drug companies that are unaware that their policies

exclude off-label uses in their assistance programs. None of these drug manufacturers currently offer assistance to patients with a diagnosis related to gender.

Are there other ways to suppress puberty if blockers aren't an option?

Yes and no.

While GnRH agonists are currently the only drugs used to pause the production of sex hormones; there are other drugs that can be used to help manage some of the secondary sexual characteristics that come with puberty. These are all oral medications that are often covered by insurance and are relatively inexpensive (\$15-\$40/month) without insurance. Progestins can be used to safely suppress menstrual bleeding, though they will not prevent the feminizing effects of estrogen in puberty.

Anti – androgen medications (spironolactone or bicalutamide) can be used to lower testosterone levels.

Let's Talk About Sex

Concerns about sexual function post-hormone therapy, or post-gender affirming surgery are common and completely valid. There are many factors that go into healthy and fulfilling sexual relationships, and many road blocks for people feeling distress in their current bodies.

Some of the factors that can affect sexual functioning and pleasure prior to gender affirming care can include:

- Anxiety about disclosing their gender identity
- Worry about being fetishized
- Worry about safety
- Negative body image

- Not wanting to be touched due to dysphoria
- Discomfort with sexual gender norms

These factors may be relieved or made less important through the initiation of genderaffirming care. It is also important for the person to remember to have patience and flexibility with themselves and their partners. Mental health plays an important role in healthy sexual function for all people, and hormones and/or surgery can only do so much. For many people of all ages and genders body/self-acceptance can be a barrier to healthy sexual relationships. Working through this is hard work, and is made harder still by gender dysphoria.

• Providers are aware of the importance of sexual health, and will check in with the patients regarding their sexual health at every visit

Hormones

- Taking cross-sex hormones will usually relieve at least some gender dysphoria after an appropriate period of time.
- Studies have shown that hormone therapy is also associated with a decrease in sexual distress for most patients within 3-6 months
- Initiating hormone therapy can cause a temporary decrease in sexual desire for some people (more common with estrogen use), but sexual desire will usually return to baseline after about 3 months of hormone therapy.
- Taking hormones can also interfere with some aspects of sexual function in some people (ability to sustain erections, ability achieve orgasm, ability of vagina to maintain lubrication and elasticity).
- These side effects can be mitigated if the person is still interested in continuing sexual play with their natal genitalia.
- Erectile dysfunction medications such as sildenafil (Viagra) and tadalafil (Cialis) can help initiate and sustain erections, and spironolactone doses can be adjusted to preserve erectile function.
- Topical estrogen creams can be applied vaginally to decrease vaginal dryness and irritation that may result from testosterone usage.

Gender-affirming Surgery

This is not an option offered at the Adolescent Medicine Clinic.

Research is lacking, and often comes from lower-quality studies (small sample sizes, no control/comparison groups), however what research there is supports the idea that trans people have quality sexual outcomes post-gender affirming surgeries.

- A study on vaginoplasty found that 90% of trans females who had the surgery reported that they were able to orgasm with 75% reporting that their orgasms were either the same or more intense than before
- Another study reported that a year after vaginoplasty, 81% of patients had initiated sexual intercourse, and 96% reported clitoral sensitivity
- Research on phalloplasty and metoidioplasty show generally positive outcomes, with negatives being noted as decreased phallic sensation and the inability to penetrate which negatively impacted sexual wellbeing