

INFORMED CONSENT

for

TESTOSTERONE BLOCKING TREATMENT

and transgender hormonal manipulation.

Transgender Clinic

I have approached GenderGP for help with hormonal manipulation to help me become more female in appearance.

I will have email access to advice and should I wish to go ahead, then I will have a telephone consultation every three to six months to assess and monitor my progress. If I have any problems then I can ask GenderGP for advice.

I understand that the medication is prescribed by GenderGP on a private prescription but I will have to pay for the actual medication to the pharmacy that dispenses it to me.

I understand that I must have blood tests, and that these can either be done by my own GP or be done by a home testing kit that is sent back to the pharmacy.

Consent

I agree that I have had the implications of taking medication to reduce the production of testosterone, or its effects, explained to me in full by GenderGP.

I agree to read the leaflets of any medication fully, before taking any treatment and to discuss any queries with GenderGP or my GP.

I understand that it may be necessary to disclose that I am taking this medication to any other doctors who may treat me for any condition in the future.

I understand that these are unlicensed uses of these medications and that all risks and liabilities of taking this medication lie with me.

I understand that this is a remote service and I must not use it as an emergency service. If I ever need a doctor in an emergency then I will contact my GP or local hospital in the usual way.

Effect of Testosterone Blocking Medication

If it is deemed necessary, I may be treated with medication to reduce the production of testosterone. As a result, I expect to experience less frequent, less firm erections; these changes are usually reversible. In the longer term, the size of the genitalia will be reduced. Reproductive capacity will be limited after prolonged treatment; I understand that I may become permanently infertile.

I have had the opportunity to discuss, with my clinician, the effects of the proposed medication and any side effects I may experience, and to clarify any points I did not understand.

I understand that I will require training to self-administer the injections or I will ask a trained healthcare professional to administer them for me. I understand that I must dispose of any needles in a sharps bin and arrange for collection of the bin according to the instructions on the bin.

I understand that the use of testosterone blocking medication in this way comes under the heading of 'off-label' or 'unlicensed' as defined by NICE and GMC.

Potential Risks and Negative Side Effects of Testosterone Blocking Hormones

I understand that this medication may cause: deep vein thrombosis; pulmonary embolism; damage to the liver; lethargy; hot flushes and sweating; and possibly depression. I understand that I will be at increased health risk if any of the following pre-existing factors apply: cigarette smoking; obesity; advanced age; heart disease;

hypertension (high blood pressure); clotting abnormalities; malignancy (cancer); endocrine abnormalities; alcohol and/or drug misuse.

Warning — who should not take oestrogen?

It should not be used by anyone who has a history of:

- an oestrogen-dependent cancer
- blood clots that could or did travel to the lungs

It 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 oestrogens are present
- has diabetes
- has eye problems such as retinopathy
- 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
- is obese
- smokes cigarettes

Effects of Oestrogen

As a result of taking oestrogen I expect to experience: some breast growth; some redistribution of body fat to that approximate to a female pattern; decreased upper body strength; softening of skin; decrease in body hair; a slowing of the loss of scalp hair; decreased fertility and testicular size and less frequent, less firm erections. Some of these changes are reversible, but breast enlargement, which will occur slowly over a period of up to two years, will not completely reverse after treatment is discontinued. Where that is the case, the remaining breast tissue can only be removed surgically. In the longer term, the size of the genitalia will be reduced. I may become permanently infertile after prolonged treatment.

I have had the opportunity to discuss, with GenderGP, the effects of the proposed medication and any side effects I may experience, and to clarify any points I did not understand.

I understand that the use of oestrogen in this way comes under the heading of 'off-label' or 'unlicensed' as defined by NICE and GMC.

Feminising Effects

I know that oestrogen or anti-androgens — or both — may be prescribed to help me appear less like a man and more like a woman.

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 if I am taking oestrogen I will probably develop breasts.

I know it can take several years for breasts to get to their full size.

I know the breasts will remain, even if I stop taking oestrogen.

I know I should examine my breasts as soon as they start growing.

<http://www.nhs.uk/chq/pages/1740.aspx?CategoryID=60&SubCategoryID=182>

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 oestrogen or by something else.

I know that no one knows if taking oestrogen increases the risk of breast cancer.

I know that the following changes are usually not permanent — they are likely to go away if I stop taking the medicines.

I know my 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 know I will probably have less fat on my abdomen and more on my buttocks, hips, and thighs. It will be redistributed to a more female shape, changing from apple shape to pear shape.

I know that if I have male pattern baldness it may slow down, but probably not stop completely. It is also very likely that hair that has been lost will not grow back.

I know I may lose muscle and strength in my upper body.

I know that my skin may become softer.

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

I know my sperm may no longer get to mature. This could make me less able to cause a pregnancy. I also know I might never produce mature sperm again, but I know that it's also possible that my sperm could still mature. So, I know that I might get someone pregnant if we have vaginal intercourse and we don't use birth control.

I am aware of the options available for sperm banking.

I know that my testicles may shrink down to half their size. Even so, I know that I will need regular check-ups for them.

I know that I won't have as much seminal fluid when I ejaculate.

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 get hard enough for penetrative sex.

I know that I may have less sex drive.

I know this treatment may (but is not assured to) make me permanently unable to make a woman pregnant.

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

I know the hair of my beard and moustache may grow more slowly than before. It 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 become more like a woman's.

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.

I know if I have any concerns about these issues, you can make referrals for me to help me explore other treatment options.

Potential Risks and Negative Side Effects of Oestrogen / Anti-androgens

I understand that the most likely side effects are: venous thrombosis; pulmonary embolism; benign pituitary prolactinoma (non-malignant tumour in the brain); weight gain; mood swings; liver disease; gallstones; breast cancer; high blood pressure and diabetes mellitus.

I understand that I will be at increased risk of unwanted side effects if any of the following pre-existing factors apply: cigarette smoking; obesity; alcohol and/or drug misuse and advanced age.

I agree to take the hormones in the dosage prescribed by my clinician and undertake not to take additional doses of oestrogen as this will pose an extra health risk.

I understand that other medication available on or off prescription may be contra-indicated whilst I am on hormone medication and I will inform any doctor that prescribes me medication that I am taking these hormonal manipulation drugs.

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 my body can convert extra oestrogen into testosterone, and that can slow down or stop me appearing more womanly.

I know these medicines 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 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 know my clinician can help me find advocacy and support resources.

I know that taking oestrogen increases 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 — especially if I am over 40. I know the danger is so high that I should stop smoking completely if I start taking oestrogen. I know that I can ask my clinician for advice about how to stop smoking.

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

I know taking oestrogen 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 oestrogen 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.

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

I know that oestrogen 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 oestrogen increases the risk of prolactinomas. These are non-cancerous tumours of the pituitary gland. I know 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 oestrogen.

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.

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 up on prostate problems. I know that if I am over 50, I should have my prostate evaluated every year with a prostate-specific antigen test, as applicable.

I agree to take feminising 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 feminisation 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. 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 these medicines. I agree to be evaluated if my clinician thinks I may have one of them. Then we will decide if it's a good idea for me to start or continue using them.

I know that I should stop taking oestrogen 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 it again a week after I'm back to normal or when my clinician says it's okay.

I know that using these medicines to appear more womanly is an off-label use. I know this means it is not approved by the government. 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.

Vaniqa

I understand that Vaniqa may help reduce the production of facial hair if used for a period of up to four months. I understand that it may cause acne and a rash at the application site.

Monitoring

I agree to my treatment being monitored by my clinician;

I agree to have the following tests done every year by my own doctor and to report any abnormalities to GenderGP:

- Full blood count
- Kidney function
- Liver function
- Lipids
- Glucose
- Weight
- Height
- BMI
- Blood Pressure

I agree to have the following blood tests arranged by GenderGP every three months:

- Testosterone level
- Estradiol level

Further Information

You are considering taking feminizing hormones, so you should learn about some of the risks, expectations, long term considerations, and medications associated with transition from male to female.

It is very important to remember that everyone is different, and that the extent of, and rate at which your changes take place depend on many factors. These factors include your genetics, the age at which you start taking hormones, and your overall state of health.

It is also important to remember that because everyone is different, your medicines or dosages may vary widely from those of your friends, or what you may have read in books or online. Many people are eager for changes to take place rapidly: Please remember that you are going through a second puberty, and puberty normally takes several years for the full effects to be seen. Taking higher doses of hormones will not necessarily make things move more quickly; it may, however, endanger your health.

The majority of medication that is used in treating transgender patients has not been licensed for this purpose although they are fully licensed for other patient groups. This is not because they are known to be any more dangerous or have more side effects in transgender patients, it is just that transgender care is so new in UK medicine that the drug companies have not yet managed to acquire proper licensing for them yet although this is likely to change in the near future.

This kind of prescribing is referred to as 'off-label'. More information regarding off-label prescribing is found on the Government link below.

There are four areas where you can expect changes to occur as your hormone therapy progresses.

1) Physical

The first changes you will probably notice are that your skin will become a bit drier and thinner. Your pores will become smaller, and there will be less oil production. You may become more prone to bruising or cuts. You may notice that you perceive pain or temperature differently, or that things just “feel different” when you touch them. You will probably notice skin changes within a few weeks. In these first few weeks you will notice that the odours of your sweat and urine will change, and that you may sweat less overall.

You will also notice small “buds” developing beneath your nipples within a few weeks of starting your treatment. These may be slightly painful (especially to the touch) and uneven between the right and left side. This is normal, and is the normal course of breast development. The pain will diminish somewhat over the course of several months.

Breast development is quite variable from person to person. Not everyone develops at the same rate, and most transgender women can only expect to develop an “A” cup or perhaps a small “B” cup, sometimes only after many years of hormone therapy. Like non-transgender women, the breasts of transgender women vary in shape and size, and are sometimes different sizes or shapes between the right and the left.

Weight will begin to redistribute around your body. Fat will begin to collect around your hips and thighs, and the fat under your skin throughout your body will become a bit thicker, giving your arms and legs less muscle definition and a smoother appearance.

Hormones will not have a significant effect on the fat in your abdomen (otherwise known as your “gut”). Your muscle mass will decrease significantly, as will your strength (though you should continue to exercise to maintain your muscle tone as well as your general health). Depending on your diet, lifestyle, genetics, and starting weight and muscle mass, you may gain or lose weight once you begin HRT.

The fat under the skin in your face will increase and shift around to give your eyes and face in general a more female appearance. Please note that your bone structure (including your hips, arms, hands, legs and feet) will not change. The facial changes can take up to 2 years or more to see the final result; It is usually a good idea to wait at least 2 years after beginning HRT before considering any drastic facial feminisation procedures.

The hair on your body, such as your chest, back and arms will decrease in thickness and will grow at a slower rate. It may not all go away, however, and some people may need electrolysis or laser to help reduce unwanted body hair. Your beard may thin a bit and grow a bit slower; however, it will rarely go away completely without electrolysis or laser treatments. If you have had any scalp balding, this should slow or stop, though the amount that will grow back is variable.

Some people may notice minor changes in shoe size or height. This is not due to bone changes, but due to changes in the ligaments and muscles of your feet.

2) Emotional.

Your overall emotional state may or may not change, this varies from person to person. Puberty is a roller coaster of emotions, and the second puberty that you will experience during your transition is no exception. You may find that you have access to a wider range of emotions or feelings, or have different interests, tastes or pastimes, or behave differently in relationships with other people. While psychotherapy is not for everyone, most people would benefit from a course of supportive psychotherapy while in transition, to help you explore these new thoughts and feelings, and get to know your new self.

3) Sexual.

Soon after beginning hormone treatment, you will notice a decrease in the number of erections that you have. When you do have an erection, it will be less firm, and will not last as long. You may lose the ability to penetrate. You will still have erotic sensation, and will still be able to orgasm. However, when you do orgasm, it may be “dry”. You may find that there are different sex acts or different parts of your body that bring you erotic pleasure. Your orgasms will feel different, with more of a “whole body” experience, less peak intensity, and longer duration. Your testicles will shrink to less than half their original size, or less. In nearly all cases, this does not affect the amount of scrotal skin available for future genital surgery.

4) Reproductive.

You must assume that within a few months of beginning hormone therapy, you will become permanently and irreversibly sterile. While some people may be able to maintain a sperm count on hormone therapy, or have their sperm count return after stopping hormone therapy, you must assume that this will not be the case for you. If you think that there might be any chance that you may, in the future, want to parent a child using your own sperm, you should speak to the doctor about preserving your sperm in a sperm bank.

You should store your sperm before beginning any hormone therapy.

Also, if you are on hormones but remaining sexually active with a woman who is able to become pregnant, you should always continue to use a birth control method to prevent unwanted pregnancy.

Many of the effects of hormone therapy are reversible, if you stop taking them. The degree to which they can be reversed depend on how long you have been taking them.

Breast growth, and possibly sterility are not reversible. If you have an orchiectomy (which is removal of the testicles) or genital reassignment surgery, you will be able to take a lower dose of hormones. However, it is important to remain on at least a low dose of hormones post-op until at least age 50 years old, to prevent a weakening of the bones, otherwise known as osteoporosis.

Cross-gender hormone therapy for transwomen may include three different kinds of medicines. Oestrogen, testosterone blockers, and progesterones.

1) Oestrogen

Oestrogen is the hormone responsible for most female characteristics. It causes the physical changes of transition, as well as many of the emotional changes. Oestrogen may be given as a pill, by injection, or by a number of preparations applied to the skin, such as a cream, a gel, a spray or a patch.

Pills are convenient, cheap and effective, but they are hard on your liver and are less safe after age 35 or if you smoke. Patches can be very effective and safe, they may cost a little more than pills, and they require that you wear them at all times. Sometimes, they may irritate your skin. Creams, sprays and gels are very effective and safe, and absorb quickly into your skin. These do tend to be a bit more expensive, and may not work as well for people who still have testicles.

Risks associated with oestrogen include high blood pressure, blood clots, liver problems, stroke, and perhaps diabetes. Also, there are potential unknown risks since we have not done a lot of research on the use of oestrogen in transwomen. It is possible that in the future we may learn about more risks or side effects, particularly when using oestrogen for many years. Contrary to what many may believe, a very small amount of oestrogen is needed to deliver the maximum effect. Taking very high doses of oestrogen does not necessarily make changes happen more quickly, but it can be dangerous and harmful to your health.

There is not much scientific evidence about the risks of cancer in transgender women.

We believe that your risk of prostate cancer will go down, but we are not sure, and therefore you will still need to be tested for that cancer when appropriate. Your risk of breast cancer may increase slightly, though it will still be less than a non-transgender female. Breast cancer screening with mammograms is recommended to begin between ages 40 and 50, for people who have been on hormones for more than 2-3 years.

Oestrogen can make your liver work too hard, causing damage. Your doctor will periodically check your liver functions, cholesterol, and perform a diabetes screening test to monitor your health while on testosterone blockers.

2) Testosterone blockers.

There are a number of medicines which can be used to block testosterone. Some of these drugs block the action of testosterone in your body, and some of them also prevent the production of testosterone. Most of the testosterone blockers are very safe. The one most commonly used, spironolactone, does have some side effects. It can make you urinate excessively, especially when you first start taking it, which can make you feel dizzy or lightheaded. It is important to drink plenty of fluids when taking this medicine.

Also, spironolactone can interact with some blood pressure medicines and can be dangerous in people with kidney problems. It is important to share your full medical history and medication list with the doctor so that they can be sure there will be no interactions. People taking spironolactone must have their potassium levels checked periodically, as it can rarely get dangerously high, which can cause your heart to stop.

3) Progesterone.

Progesterone is a source of constant debate among both transwomen and providers. Progesterone has a number of reported benefits, such as improved mood, energy or libido, better breast development, or better body fat redistribution and “curves”. There is very little scientific evidence to support these claims. However, some transwomen do prefer to take progesterone and have seen some of these benefits. When you take a natural form of progesterone, your risk of things like blood clots, stroke, or cancer are minimised, but still may be increased; There simply is not enough research in this area to make an accurate prediction of your risk.

DECLARATION AND AGREEMENT

By signing this document, I am confirming that I have read all of the information herein and that I will adhere to my responsibilities related to this treatment. In particular and to reiterate:

- 1) I will ensure I have monitoring blood tests at least every 13 weeks for the duration of my treatment as mentioned in the service's information document
- 2) I will update the service with any relevant information at any time including but not limited to my medical history, medications and address
- 3) I will be honest at all times as to my personal information as well as any changes thereto

Patient Signature

Full Legal Name

Dated:

25/03/19

Associated Person's Signature (Where appropriate)

Full Legal Name

Relationship to Patient

Dated:
