

# SHARED CARE PRESCRIBING GUIDANCE FOR

## Treatment of Gender Dysphoria in Transmen (Female to Male Transsexuals)

<b>Applicable to:</b>	GPs referring patients to the Charing Cross Gender Identity Clinic
<b>Date Approved:</b>	14 March 2017
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### INTRODUCTION

This document has been prepared by Dr Leighton Seal, Consultant Endocrinologist, and the GIC's Clinical Team together with WLMHT's Chief Pharmacist.

The information contained in this document has been compiled in order to support GPs and other medical practitioners in safe prescribing and monitoring arrangements. The document outlines the roles and responsibilities of the Gender Specialists, General Practitioners and Patients and contains both a **Shared care agreement** and a patient **letter of consent** for the initiation of hormones. It is imperative that patients who take the preparations, as listed, do so under medical supervision, and are monitored as recommended.

Please ensure that the latest updates on the medications and interactions, as listed, are obtained from the BNF.

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### LETTER FROM LEAD CLINICIAN and CONSULTANT ENDOCRINOLOGIST

Dear Colleague

We have created this Shared Care protocol in order to ensure that patients who attend the Charing Cross Gender Identity Clinic receive a partnership of care from both their Gender Clinicians and their General Practitioners.

The medicine recommended by the GIC is usually a testosterone (e.g. Sustenon) to cause masculinisation, and which will be continued indefinitely after surgery. In some cases additional or alternative medicines are used, as outlined in the shared care protocol. Sometimes there is a need for a GNRH analogue (e.g. decapeptyl or zoladex) to suppress oestrogen prior to surgery.

In view of the fact that the patients will be having long-term maintenance treatment, it is in their best interests for their GP to prescribe and monitor their treatment, with support from our clinic as necessary. The standardised mortality rate for transsexuals is 1.0, demonstrating that longer term testosterone therapy is not detrimental or harmful. That is to say, patients are no more likely to die as a result of taking this treatment than if the GP did not prescribe at all.

Although not all these medicines are licensed for the treatment of gender dysphoria (nor are they likely to be), they are medicines with which, in our experience, GPs will be familiar. The doses of testosterone are the same that would usually be prescribed, for hormone replacement in a born male.

There is a comprehensive programme for assessment and evaluation of patients referred to this clinic, into which GPs and any relevant secondary care clinicians are routinely copied. When all these assessments have been undertaken, the decision may be taken to recommend medication.

**In the event that a written recommendation for hormone therapy is made, we would be grateful if arrangements can be made by the patient's GP to see the patient within 2 weeks in order to initiate the treatment.**

We hope that this will give GPs enough information to feel confident to prescribe the maintenance medication for their patients as specified. If you have any questions, or would like more information, you are welcome to contact us.

Yours sincerely



**Dr James Barrett**  
Lead Clinician, Gender Identity Clinic



**Dr Leighton Seal**  
Consultant Endocrinologist



## SHARED CARE PRESCRIBING GUIDELINE

### Treatment of Gender Dysphoria in Transmen (Female to Male Transsexuals)

#### 1. CIRCUMSTANCES WHEN SHARED CARE IS APPROPRIATE

- The GP will commence prescribing when both the consultant and GP concur the patients condition is psychologically stable or predictable.

#### 2. AREAS OF RESPONSIBILITY

##### Specialist Gender Identity Clinic Team/Consultant Responsibilities

- Establish or confirm diagnosis and assess patient suitability for treatment
- Baseline monitoring:  
baseline bloods
- Discuss treatment with patient and ensure they have a clear understanding of benefits and side-effects of treatment, including dose adjustments and how to report any unexpected symptoms  
The specialist team provides the patient with information and advice, supported by a written information booklet
- Obtain signed consent for hormonal treatment
- Fax a signed shared care guideline with patient details completed to GP for consideration of shared care request
- Contact GP directly if response to shared care request has not been received within 2 weeks
- Monitor treatment according to local guideline (see Page 5) and advise patient and GP on dose titration of medicines.

##### **After agreement to share care; Specialist team to**

- Inform GP when patient is stable
- Inform GP of abnormal monitoring results and any changes in therapy prescribed by the GP, including the need to discontinue if appropriate
- Evaluate adverse events reported by GP or patient and communicate outcome to GP
- Carry out ongoing monitoring and follow up accordingly to shared care guidelines including continued need for therapy.

##### **Consultant/Gender specialist Nurse:**

The Gender specialist nurse will provide training, support and advice for General Practitioners, Community Pharmacists, District Nurses, and the patient.

##### GP RESPONSIBILITIES

- Consider shared care proposal and if in agreement to respond within 2 weeks of receipt
- If do not agree to shared care discuss with requesting consultant or local PCT medicines management team within 2 weeks of receipt of shared care request

##### **After agreement to share care**

- Prescribe dose as advised by the Specialist Team and discussed with the patient
- Monitor general health of patient and check adverse effects as appropriate; ensure patient is aware of warning symptoms and how to report them
- Inform specialist consultant of suspected adverse effects and also report via yellow card scheme if necessary
- Stop treatment on advice of specialist or immediately if urgent need arises
- Check compatibility interactions when prescribing new or stopping existing medication
- Carry out monitoring and follow up according to shared care guideline
- Discuss any abnormal results with specialist consultant and agree any action required

Only ask specialist to take back prescribing should unmanageable problems arise. Allow an adequate notice period.

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### 3. PATIENT'S RESPONSIBILITIES (add specific additional responsibilities where applicable)

- Keep a copy of management booklet and other information provided by Gender Identity Clinic, including consent to treatment, to take along when seeing GP
- Take medicines as agreed and prescribed
- Report any adverse effects to GP or hospital doctor
- Do not share medicines
- Attend appointments for review as necessary
- Always inform the Specialist team and GP of all medication being taken, whether prescribed or bought

### 4. COMMUNICATION AND SUPPORT

#### Gender Identity Clinic contacts:

Dr James Barrett, Lead Clinician, Gender Identity Clinic  
Direct phone number 0208 483 2801

e-mail [james.barrett@wlmht.nhs.uk](mailto:james.barrett@wlmht.nhs.uk)

WLMHT Chief Pharmacist  
Trudi Hilton 0208 354 8338

email [Trudi.hilton@wlmht.nhs.uk](mailto:Trudi.hilton@wlmht.nhs.uk)

## SHARED CARE PRESCRIBING GUIDELINE

Attach patient addressograph or

Insert patient details

Patient name

Patient ID

Date of Birth

### Treatment of Gender Dysphoria in Transmen (Female to Male Transsexuals)

#### 5. CLINICAL INFORMATION

<b>Indication(s):</b>	Treatment of gender identity disorder following psychiatric assessment at Gender Identity Clinic.
<b>Place in Therapy:</b>	<p>Hormonal therapy will usually be recommended after the client has been assessed by 1-2 mental health practitioners (MHP) following a period of assessment by them. Consistent with the Joint society guidelines. Usually the patient lives in their preferred gender role full time for a period, which is not usually less than three months prior to the initiation of hormone therapy. This will be adhered to in the vast majority of cases. Commencement of hormonal therapy should generally be deferred until the client has demonstrated consolidation of their gender identity during 'real-life experience', and they have made progress in mastering the problems their new social role has brought.</p> <p>The use of hormonal manipulation in the treatment of transsexual individuals is hampered by a lack of any randomised controlled trials to assist in our therapeutic decisions. There has however been a significant amount of experience in the treatment of this condition over the last 30 years, using several well-established hormonal protocols, and the totality of the available evidence demonstrates that, for carefully selected patients, hormone therapy is a safe and effective means of alleviating the potentially debilitating condition of gender dysphoria.<sup>1,2</sup> Indeed Sustanon is licensed as supportive therapy for female-to-male transsexuals(1)</p>
<b>Dose &amp; route of administration:</b>	<p><b>Testosterone to cause masculinisation:</b></p> <p>Injectable Testosterone Sustenon, Testosterone Enthanate and Viormone can be seen as equivalent Doses of short acting testosterone preparations at 250mg 2-4 weekly are usually adequate to suppress menstruation and the aim of therapy is to achieve testosterone levels in the high normal male range (25-30nmol/l) 1 week after the injection and to have a trough level at the bottom of the normal male range (8-12nmol/l) on the day the injection is due before the injection is administered. Monitoring should be performed in the steady state i.e. following at least 3 injections(2). Titration of the peak value is achieved by varying the dose administered with each injection, whilst the trough level is controlled by changing the length of time between the injections(2). If the levels are too high it is best to adjust the dosing frequency first and then the dose. Alterations are generally made by weekly intervals i.e. the dose is administered 2-6 weekly and the doses altered by 50mg at a time which is an alteration of 0.2ml of a 250 dose mg vial.</p> <p><b>Second line.</b> Topical gel preparations 25-100mg (testim, testsogel, Tostran). The usual starting dose is 50mg daily (one sachet of gel or 6 squirts of tostran) and the levels titrated to achieve a plasma testosterone in the middle adult range 15-20nmol/l. The level should be measured 4-6 hours after the gel application and there should be no gel applied to the arm on that day(2).</p> <p><b>Third Line</b> In cases where the short acting injection cause side effects e.g. mood swings or injection site reactions and gel preparations are not suitable i.e. go not give reliable</p>

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	<p>levels, patient is very hirsute or there is a significant risk of transfer of the testosterone gel to others the long acting Testosterone Undecanoate (Nebido) may be used(2). It may be considered as a more cost effective therapy when the patient has been established on testosterone treatment as it requires fewer GP visits and therefore less clinical time to administer. Nebido as a long acting preparation requires loading as below.</p> <p><b>Stage One:</b> Nebido 1000mg accompanied by Sustanon 250mg (or Testosterone Enantate or Virormone) both given intra muscular. Or if no Sustanon or Enantate available then two weeks of Testim gel 50mgs/5grm packet one applied daily.</p> <p><b>Stage Two:</b> Six weeks later a Nebido 1000mg intramuscular</p> <p><b>Stage Three:</b> Six weeks later a Nebido 1000mg intramuscular This completes the loading phase</p> <p><b>Stage Four:</b> The next Nebido 1000mg is given <b>12 weeks</b> later, (i.e. 24<sup>th</sup> week) on the 10<sup>th</sup> and 11<sup>th</sup> week coming up to the 12<sup>th</sup> week injection please take bloods for Plasma testosterone levels and on the 12<sup>th</sup> week as well as the Plasma testosterone bloods will also be required for Full Blood Count, Fasting Lipids, Glucose and Liver Function Test.</p> <p><b>Stage Five:</b> Nebido 1000mg intramuscular every 12 weeks.</p> <p><b>Gonadotrophin analogue to suppress oestrogen (in addition to treatments to increase levels of oestradiol):</b></p> <p>If testosterone therapy to adult male levels does not suppress menstruation or amenorrhoeic cycling then GnRH analogues can be used to suppress ovarian function(3).</p> <p>Decapeptyl 11.25mg (s.c.) every 12 weeks is the most cost-effective option and given IM which is often preferred by patients</p> <p>Goserelin i.m.10.8mg every 12 weeks</p> <p><b>Alternatives:</b></p> <p>Goserelin 3.75mg monthly subcutaneously</p> <p>Leuprorelin i.m. 11.25mg every 3 months</p> <p>Leuprorelin i.m. 3.75mg monthly</p> <p><b>Rarely:</b></p> <p><b>Progestins may be used inhibit menstruation.</b></p> <p>Norethisterone 5mg t.d.s.</p> <p>Medroxyprogesterone acetate 10mg t.d.s.(3)</p>
<b>Duration of treatment</b>	<p>Testosterone Long Term</p> <p>GnRH analogues until gender reassignment surgery or oophorectomy</p>
<b>Criteria for stopping treatment</b>	<p><b>Preoperative</b></p> <p>Significant side effects / lack of response at adequate doses / client self discharges from the GIC</p> <p><b>Postoperative.</b></p> <p>Development of significant contraindication to testosterone use</p>
<b>Monitoring Requirements before Starting Treatment:</b>	<p><b>Consultant/Gender Nurse Specialist</b></p> <p>Psychiatric assessment of patient's suitability for treatment. Screening for self-administered substances, Measurement of LH, FSH, Testosterone, Estradiol,</p>

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	<p>SHBG, Prolactin, Dihydrotestosterone, PSA, Weight/height/BMI, Blood pressure, Lipid profile, LFTs, Glucose, and renal function if indicated</p>
<p><b>Monitoring requirements once stable, including frequency:</b></p>	<p><b>Consultant/Gender nurse specialist:</b> to advise GP on dose alterations required based on hormone and other monitoring information provided.</p> <p><b>GP:</b></p> <p>Every 6-12 months</p> <p>Testosterone levels until stable</p> <p>FBC LFTs, Blood pressure, lipids, glucose, Weight/height/BMI</p>
<p><b>Follow up arrangements</b></p>	<p><b>Consultant/Gender specialist Nurse:</b></p> <p>The Gender specialist nurse will provide training, support and advice for General Practitioners, Community Pharmacists, District Nurses, and the patient. Patients will be reviewed at WLMHT three monthly initially and then six monthly thereafter.</p> <p><b>GP:</b> The primary care team will be responsible for the ongoing prescribing of testosterone and ovarian inhibitors only once the patient has been established under the gender treatment protocol on therapy and will continue to act as the primary contact for general healthcare.</p> <p>To refer to specialist team if any significant developments or deterioration occur, such as occurrence of side-effects, worsening of symptoms or complications of masculinising hormone therapy.</p>
<p><b>Prescribing Responsibilities: As above</b></p>	<p><b>Gender Identity Clinic:</b> The specialist team will take responsibility for the recommendation for treatment, counselling about risks and benefits of therapy and ongoing responsibility for recommending alterations to therapy until patient is stabilised on therapy</p> <ul style="list-style-type: none"> <li>• To oversee the whole programme of assessment and treatment, including dose adjustment as necessary to reach a maintenance level</li> <li>• To liaise with the GP on arrangements for stopping medication prior to genital reconstructive surgery, and restarting it afterwards</li> </ul> <p>To advise GP on any problems arising from this treatment which may need a dose adjustment or a change in medication</p> <p><b>GP:</b> The GP will take on prescribing if happy to agree shared care.</p>
<p><b>Practical issues including other relevant advice/information: Medication information, particularly in relation to potential interactions, can be found in the latest edition of the BNF</b></p>	<p>The side effect profile and safety is identical to that seen in genetic males having testosterone replacement for hypogonadism. The only difference in female to male transsexuals is the need to monitor the effects of testosterone on the uterus until the patients undergoes hysterectomy.</p> <p>1. Polycythaemia</p> <p>Testosterone replacement can be associated with polycythaemia and this increase in blood viscosity can lead to an increased incidence of stroke. In those that have a haematocrit above 48% there appears to be an increased risk of stroke(4). This can occur even in young subject as both stroke and myocardial infarction have been reported athletes that abuse testosterone(5).</p> <p>Polycythaemia is seen more when injectable testosterone is used and appears to be proportional to the amount of supraphysiological testosterone that is administered. For this reason the aim of treatment is to keep the peak testosterone within the upper normal male range i.e. 25-30 nmol/l whilst keeping the trough level at the bottom of the normal male range (6-12nmol/l). Polycythaemia is seen much less with other formulations.</p> <p>Polycythaemia usually responds to a decrease in the dose of testosterone especially if this is changed to a non injectable formulation. When this is inadequate, regular venesection to bring the haematocrit down into the normal range can be instituted and this allows the testosterone therapy to be continued. The frequency of the venesection is variable but it often in this situation needs to be performed 4-6 weekly to control the haematocrit.</p>

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	<p><b>2. Liver Dysfunction</b>                  The incidence of hepatic dysfunction with alkylated steroid preparations such as methyl testosterone was high. These anabolic steroids are no longer used in routine testosterone replacement and so the incidence of hepatic dysfunction associated with testosterone use is less. In one series however transient increases in liver function enzymes was seen in 4.4% of female to male transsexuals and this was prolonged (&gt;6months) in 6.8%(6).                  These are usually minor and do not require cessation of treatment. Routine monitoring of the liver function in patients on testosterone replacement is recommended. Minor derangement of Liver function, with increases in liver enzyme levels to less than twice the upper limit of normal do not require withdrawal of testosterone therapy. Screening for other causes of hepatic dysfunction should be performed and ultrasound scanning of the liver to exclude any hepatic lesion or the presence of gall stones.                  There have been no reports of liver tumours with testosterone esters.</p> <p><b>3. Lipid Profile</b>                  The administration of testosterone in female to male transsexuals is associated with an increase in triglyceride and a decrease in plasma HDL levels both of which are proatherogenic. However total cholesterol and LDL cholesterol remain unchanged(7). It is interesting that these changes in lipid profile so not appear to translate into an alteration in cardiovascular risk as there is no increase in cardiovascular mortality in treated male to female transsexuals, indeed the myocardial infarction rate is approximately half that expected in the general male population(8).</p> <p><b>4. Gynaecological Malignancy</b>                  Testosterone can be aromatised to oestradiol. The reported risk of endometrial hyperplasia is 15% in male to female transsexuals(9). Monitoring of the endometrial thickness by ultrasound scanning biannually is recommended. It is our usual practice to recommend hysterectomy after 2 years of testosterone therapy. If irregular bleeding occurs then the patient should undergo ultrasound scanning and endometrial biopsy to rule out any neoplastic alteration in the endometrial epithelium.</p> <p><b>5. Obstructive Sleep Apnoea</b>                  Testosterone therapy exacerbates the symptoms of obstructive sleep. In a female to male transsexual who has symptoms of obstructive sleep apnoea symptom scores should be assessed and referral made to a specialist in sleep disorders for treatment if the patient displays and deterioration in their condition.</p>
<p><b>Information provided</b></p>	<p>Patients are given a copy of the Clinic's Management Booklet which is also available for GPs <a href="http://www.wlmht.nhs.uk/gi/gender-identity-clinic">www.wlmht.nhs.uk/gi/gender-identity-clinic</a> . It is based on The Practical Management of Hormonal Treatment in Adults with Gender Dysphoria<sup>13</sup>.</p>

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<p><b>Evidence Base for treatment and Key references:</b></p>	<ol style="list-style-type: none"> <li>1. 2012. Electronic Medicines Compendium. <a href="http://www.medicines.org.uk/emc/medicine/5164/SPC/">http://www.medicines.org.uk/emc/medicine/5164/SPC/</a>.</li> <li>2. J, S.L. 2009. Testosterone Replacement Therapy. <i>Medicine International</i> 37:445-449.</li> <li>3. Barrett, J.D. 2007. <i>Transsexual and other disorders of gender identity : a practical guide to management</i>. Abingdon: Radcliffe. xii, 298 p., [298] p. of plates pp.</li> <li>4. Krauss, D.J., Taub, H.A., Lantinga, L.J., Dunsky, M.H., and Kelly, C.M. 1991. Risks of blood volume changes in hypogonadal men treated with testosterone enanthate for erectile impotence. <i>J Urol</i> 146:1566-1570.</li> <li>5. Ferenchick, G.S. 1991. Anabolic/androgenic steroid abuse and thrombosis: is there a connection? <i>Med Hypotheses</i> 35:27-31.</li> <li>6. van Kesteren, P.J., Asscheman, H., Megens, J.A., and Gooren, L.J. 1997. Mortality and morbidity in transsexual subjects treated with cross-sex hormones. <i>Clin Endocrinol (Oxf)</i> 47:337-342.</li> <li>7. Elbers, J.M., Giltay, E.J., Teerlink, T., Scheffer, P.G., Asscheman, H., Seidell, J.C., and Gooren, L.J. 2003. Effects of sex steroids on components of the insulin resistance syndrome in transsexual subjects. <i>Clin Endocrinol (Oxf)</i> 58:562-571.</li> <li>8. Asscheman, H., Gooren, L.J., and Eklund, P.L. 1989. Mortality and morbidity in transsexual patients with cross-gender hormone treatment. <i>Metabolism</i> 38:869-873.</li> <li>9. Futterweit, W. 1998. Endocrine therapy of transsexualism and potential complications of long-term treatment. <i>Arch Sex Behav</i> 27:209-226.</li> </ol>
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NB: for full details of adverse effects and drug interactions refer to latest Summary of Product Characteristics [emc.medicines.org](http://emc.medicines.org)

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### SHARED CARE PRESCRIBING AGREEMENT

(Appendix ia)

#### 6. CIRCUMSTANCES WHEN SHARED CARE IS APPROPRIATE

- The GP will commence prescribing when the clinicians from the GIC judge the patient's condition as both medically and psychologically stable or predictable.

#### 7. AREAS OF RESPONSIBILITY

<b>Specialist Gender Identity Clinic Team/Consultant Responsibilities</b>
<ul style="list-style-type: none"> <li>▪ Establish or confirm diagnosis and assess patient suitability for treatment</li> <li>▪ Baseline monitoring of bloods by Consultant Endocrinologist:</li> <li>▪ Discuss treatment with patient and ensure they have a clear understanding of benefits and side-effects of treatment, including dose adjustments and how to report any unexpected symptoms The specialist team provides the patient with information and advice, supported by written information as required.</li> <li>▪ Obtain signed consent for hormonal treatment</li> <li>▪ Send a signed shared care guideline with patient details completed together with relevant clinical information to GP for consideration of shared care request</li> <li>▪ Monitor treatment according to clinical guidance and advise patient and GP on dose titration of medicines.</li> </ul> <p><b>Ongoing Care Arrangements: Specialist team to</b></p> <ul style="list-style-type: none"> <li>▪ Write to GP following clinic contacts</li> <li>▪ Inform GP of abnormal monitoring results and any recommended changes in therapy prescribed by the GP, including the need to discontinue if appropriate</li> <li>▪ Evaluate adverse events reported by GP or patient and communicate outcome to GP</li> <li>▪ Make arrangements for ongoing monitoring and follow up accordingly to shared care guidelines including continued need for therapy.</li> </ul> <p><b>Consultant/Gender specialist Nurse:</b> The Gender specialist nurse will provide training, support and advice for General Practitioners, Community Pharmacists, District Nurses, on request.</p>
<b>GP RESPONSIBILITIES</b>
<ul style="list-style-type: none"> <li>▪ Prescribe treatment as advised by the Specialist Team and previously discussed with the patient</li> <li>▪ Monitor general health of patient and check for adverse effects as appropriate</li> <li>▪ Inform specialist consultant of suspected adverse effects</li> <li>▪ Stop treatment on advice of Gender Clinician or immediately if urgent need arises</li> <li>▪ Check compatibility interactions when prescribing new or stopping existing medication</li> <li>▪ Carry out monitoring and follow up according to shared care guideline</li> <li>▪ Discuss any abnormal results with Gender Clinician and agree any action required</li> </ul>
<b>PATIENT'S RESPONSIBILITIES</b>
<ul style="list-style-type: none"> <li>▪ Keep a copy of information provided by Gender Identity Clinic, including consent to treatment, to take along when seeing GP</li> <li>▪ Take medicines as agreed and prescribed</li> <li>▪ Report any adverse effects to GP or hospital doctor at the earliest opportunity</li> <li>▪ Ensure that you attend for tests as requested by your Gender Clinician or GP</li> <li>▪ Do not share medicines</li> <li>▪ Attend appointments for review as necessary</li> <li>▪ Always inform the Specialist team and GP of all medication being taken, whether prescribed or bought</li> </ul>

**SHARED CARE PRESCRIBING GUIDELINE**  
**SHARED CARE PRESCRIBING AGREEMENT**  
(Appendix ib)

**GENDER CLINICIAN**

I confirm that I have assessed the patient today,

Patient Address:  
Patient name:  
Patient ID:  
Date of Birth:

and it is my clinical recommendation that the following treatment is prescribed:

Furthermore, the “Areas of Responsibility” have been covered and I agree to the “on-going care arrangements”.

**Signature:**

**Print Name:**

**Date:**

## SHARED CARE PRESCRIBING GUIDELINE

### PATIENT CONSENT LETTER FOR INITIATION OF HORMONES (Appendix ii)

I, ..... (print name) met with Dr  
..... today, ..... (date)

I can confirm that we have discussed the potential effects, side effects and expectations of Hormone therapy. In addition we have also discussed the potential effects that this therapy will likely have on my fertility.

Furthermore I confirm that I will adhere to the “Patient Responsibilities” as outlined in the shared care agreement.

..... (signature)