Specification for a Local Enhanced Service for the Administration of Hormone Therapy in Primary Care for Adult Trans and Non-binary Patients under the direction of the Local Gender Team

1. Introduction

All practices are expected to provide essential services and those additional services they are contracted to provide to all their patients under the GMS contract. The specification of this service therefore outlines the general and more specialised service to be provided that is beyond the scope of essential services. No part of the specification by commission, omission or implication defines or redefines essential or additional services.

The overall aim of this specification is for GP practices to be able to prescribe and administer hormone therapy on behalf of the Hywel Dda Local Gender Team and should be read alongside the Shared Care Protocol at Appendix 1.

This Local Enhanced Service is not intended to replace the current Service provided under the Local Enhanced Service The Hormone Treatment Scheme for Adult Trans and Non binary Patients in Primary Care but is in addition to.

2. Background

For many years Gender Identity Services for patients resident in Wales have been commissioned by the Welsh Health Specialist Services Committee (WHSSC) from the West London Gender Identity is Clinic (WLGIC). WHSSC has designed and is implementing a graduated model to support the care of patients with gender dysphoria/incongruence resident in Wales. The Cardiff clinic (a tertiary gender identity clinic) started seeing adult patients in September 2019 and receives direct GP referrals for those aged 18 years and over.

This Local Enhanced Service is designed to assist the Local Gender Team to support adult patients (aged 18 years and over) to administer treatments with optimisation of hormone therapies in a safe and supported way.

3. Delivery

This Local Enhanced Service will be offered to each GMS contractor (in relation to the registered patients of that GMS contractor)

It is the responsibility of the contractor to ensure that each Health Care Professional undertaking this Local Enhanced Service has the necessary skills, training, competence and experience in order to provide the service.

4. The Service Description

This Local Enhanced Service will support the ongoing care of patients by commissioning GMS contractors to:

- **Prescribe** the maintenance treatment(s) as requested by the Local Gender Team prescriber
- **Be vigilant** for potential drug interactions or adverse reactions and report via the yellow card scheme if necessary - It is the responsibilities of all prescribers to report all serious reactions to the MHRA via the 'yellow card scheme' - https://yellowcard.mhra.gov.uk/
- **Stop Treatment** on specialist advice or immediately if the urgent need arises
- **Notify** the Local Gender Team and the Welsh Gender Team via the admin email provided of any changes to the patient's circumstances that might affect their treatment
- **Inform** the Local Gender Team and the Welsh Gender Team via the admin email provided if the patient wishes to pursue gamete storage while under the care of the GP

Payments

Each commissioned GMS contractor will be able to claim:

- A payment of [redacted] for the prescribing and administration of each Injection and/or a Gel as requested by the Local Gender Team.

- Episodes of phlebotomy undertaken as part of this shared care approach will be remunerated via a Secondary Care Initiated Phlebotomy LES.

SHARED CARE PROTOCOL: TESTOSTERONE, ESTROGEN, GONADOTROPHIN-RELEASING HORMONE (GnRH) AGONISTS and FINASTERIDE THERAPY for ENDOCRINE MANAGEMENT OF GENDER DYSPHORIA IN ADULTS

This document should be read in conjunction with the current SPC: www.medicines.org.uk/

1. Licensed indications
State if drug is being used off-label.

The medicines included in this protocol are:
Testosterone
Gels:**Testogel® 16.2 mg/g, Testavan® 20mg/g, Tostran® 2%**
Short-acting injection: This is usually **Sustanon®** or, rarely, **Delatestryl®**
Long-acting injection: **Nebido®**
Estrogen Estradiol valerate (Progynova®),Estradiol hemihydrate (Elleste Solo®, Zumenon®), gel and patches
GnRH Agonists Triptorelin (Decapeptyl®) 11.25 mg, Leuprorelin (Prostap®) 11.25 mg, Goserelin (Zoladex®) 10.8 mg subcutaneously every 12 weeks
Finasteride

These are all unlicensed ('off label') uses of these medicines and are initiated and optimised by the Local Gender Team (LGT) following assessment, diagnosis and treatment recommendation from the Welsh Gender Team. Once optimisation criteria are met, the patient's General Practitioner is invited to provide maintenance treatment on a long-term basis supported by the Local and Welsh Gender Teams.

2. Therapeutic use and background

Testosterone therapy: For most trans men, the aim of hormone therapy is to achieve serum testosterone levels equivalent to the adult male range, and in doing so simulate male puberty, a process that can take up to 5 years to complete. Some (but not all) non-binary individuals assigned female at birth use low dose testosterone therapy under specialist guidance. Treatment should start with gel (or in some cases a short-acting injection), moving to a long-acting injectable formulation provided that blood monitoring test results are satisfactory, and the patient wishes to do so.

Estrogen Hormone Replacement Therapy (HRT): This is the mainstay of medical treatment in trans women and is introduced gradually and titrated to achieve a serum estradiol level of 350-750 pmol/L. Some (but not all) non-binary individuals assigned male at birth opt for low dose estrogen (ostradiol) therapy under specialist guidance.

The use of **gonadotrophin-releasing hormone(GnRH) agonists** or **anti-androgen treatments (e.g. finasteride)** may also be required to suppress testosterone release into the female serum range

3a. Contraindications

Testosterone	Estrogen (Estradiol)	Gonadotrophin-releasing hormone(GnRH) agonists	Finasteride
Breast cancer Pregnancy Breast feeding Primary liver tumour Hypercalcaemia Acute or recent arterial disease	Breast cancer Thromboembolism • active • recurrent Thrombophilic disorders Dubin-Johnston and Rotor syndromes Acute liver disease Acute or recent arterial disease Acute porphyria	Hypersensitivity to GnRH, its analogues or any other component of the medicinal product Pregnancy & lactation	Hypersensitivity to finasteride or any of the excipients. In females due to the risk in pregnancy

3b. Cautions	Epilepsy Migraine Hypertension Predisposition to oedema Liver disease Renal insufficiency Obstructive sleep apnoea Ischaemic heart disease	Obesity Hypertension Ischaemic heart disease Single DVT Family history of thromboembolism and breast cancer Migraine with focal neurology SLE Sickle cell disease Gallstones and liver disorders	Osteoporosis or risk factors for osteoporosis Previous history of depression Previous history or risk factors for QT prolongation Patients at high-risk of for metabolic or cardiovascular disease	Hepatic impairment
4. Typical dosage regimen (adults)	**All dose adjustments will be done by secondary care. The following is for information only:**			
	Testosterone	**Estrogen (Estradiol)**	**Gonadotrophin-releasing hormone(GnRH) agonists**	**Finasteride**
	Gel: Testogel® 16.2 mg/g, Testavan® 20mg/g, Tostran® 2% **Starting dose:** approximately 40mg daily (2 pumps daily of Testoge®l/ Testavan® or 4 pumps daily of Tostran®) applied daily) to a maximum of 80mg daily. Titrate to serum testosterone level. **Testosterone target range 15-20 nmol/L** **Short-acting Injection:** Sustanon® (rarely Delatestryl®) **Starting dose:** 250mg (1mL) by intramuscular injection every 4 weeks. Titrate dose according to tough and peak level. Most patients require between 150-250mg every 2-4 weeks **Trough testosterone target range 8–12 nmol/L** **Peak testosterone target range 25–30 nmol/L** **Depot Injection** Nebido®	**Oral:** Estradiol valerate (Progynova®) Estradiol hemihydrate (Elleste Solo®, Zumenon®) **Starting dose:** 2mg daily to a maximum of 8mg daily. **Topical** (used when oral contra-indicated, not tolerated or fails to reach target range) **Gel:** (e.g. Sandrena®) **Starting dose:** 1mg daily (equivalent to 2mg oral) to a maximum of 4mg daily. **Patches:** (e.g. Evorel®, Estradot®) **Starting dose:** 50 micrograms/24 h twice-weekly to a maximum of 200 micrograms/24 h twice weekly. **Titrate all preparations to a serum estradiol target range of 350-750 pmol/L** Estradiol use in trans women over 55 years appears safe for breast health	**Triptorelin (Decapeptyl®) 11.25 mg** intramuscularly every 12 weeks • **Leuprorelin (Prostap®) 11.25 mg** intramuscularly every 12 weeks **Alternative GnRH agonist:** • **Goserelin (Zoladex®) 10.8 mg** subcutaneously every 12 weeks All are available as monthly preparations if indicated or preferred **Trans women:** Start after an oral dose of 4mg estradiol daily (or equivalent topical dose) to avoid triggering menopausal symptoms. With only the **first dose** of GnRH agonist prescribe cyproterone acetate 100mg once a day **for 14 days only**. Stop after orchidectomy; N.B: routine monitoring of serum testosterone is no longer required. **Trans men:** If the use of a progestin fails to abolish menstruation or anovulatory cycling, GnRH agonists may be used after advice from the Welsh Gender Team.	**Orally:** 5mg daily Can be continued after orchidectomy as a small amount of testosterone is secreted by the adrenal glands

	Starting dose after short-acting preparations (gel or short-acting injection): 1000mg/4mL on week 0, 6, 18, 30 and then approximately every 12 weeks adjusted according to the **trough** testosterone level (usually within 11-13 weeks). **Trough testosterone target range 15–20 nmol/L**	and can be continued life-long unless medical complication arise.		

5. Drug interactions For a comprehensive list, consult the BNF or SPC	**Testosterone**	**Estrogen (Estradiol)**	**Gonadotrophin-releasing hormone(GnRH) agonists**	**Finasteride**
	Warfarin – testosterone may enhance anticoagulant effect.	There are no drug interactions with topical estradiol. The metabolism of oral estradiol can be affected by drugs which act on liver enzymes, such as cytochrome P450. Both enzyme inducers and inhibitors have been shown to have enzyme-inducing properties when used concomitantly with steroid hormones.		No relevant drug interactions.

6. Adverse drug reactions For a comprehensive list (including rare and very rare adverse effects), or if significance of possible adverse event uncertain, consult the SPC or BNF		
	Most serious toxicity is seen with long-term use and may therefore present first to primary care. The frequency of adverse reactions is classified using the following convention: Very common (≥ 10%); common (≥ 1% and < 10%); uncommon (≥ 0.1% and < 1%); not known (cannot be estimated from the available data). **If you suspect an adverse reaction has occurred this should be reported to the Local Gender Team. Any adverse reaction to a black triangle drug, or serious reaction to an established drug, should be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) via the "Yellow Card" scheme.** https://yellowcard.mhra.gov.uk/	
	Clinical condition ***(Where possible indicate if common, rare or serious)***	**Management (*Including threshold at which to contact specialist*)**
	Testosterone The side effect profile and safety of testosterone in trans men is identical to that seen in cisgender males undergoing testosterone replacement for hypogonadism.	
	Local irritation	Rotate application/injection sites.
	Mood fluctuations	Particularly with the short-acting injectable formulation given the more pronounced peaks and troughs.

Polycythaemia	Testosterone therapy stimulates erythropoietin production11 Seek advice from Welsh Gender Team if haematocrit >0.52. Stop and seek urgent advice from a haematologist if haematocrit >0.60
Obstructive sleep apnoea	Testosterone therapy may exacerbate the symptoms of obstructive sleep apnoea. Refer to a specialist in sleep disorders if the patient's condition deteriorates.
Abnormal lipid profile	Testosterone replacement in trans-men is associated with an increase in triglycerides and a decrease in plasma HDL levels. However, these changes do not appear to alter cardiovascular mortality. Normal cardiovascular risk assessment for trans gender applies.
Future fertility	Patients are counselled that treatment with testosterone may temporarily or permanently impair fertility and counselled about their future reproductive options.
Liver dysfunction	LFT abnormalities are usually minor and do not require treatment to be stopped. An increase in liver enzymes to more than three times the upper limit of normal requires suspension of treatment; contact the Welsh Gender Team
Estradiol Although higher doses (than the licensed doses for HRT in women) are used, estrogen is usually very well tolerated.	
Thromboembolic disease	Newer oestrogens (and formulations) have a dramatically lower DVT risk than older oestrogens.
Breast cancer	Risk of breast cancer secondary to estrogen therapy is thought to be lower than for cisgender women. However, uptake of the National Breast Screening program is strongly advised
Prostate cancer	Incidence is reduced secondary to estrogen therapy, but symptoms should be investigated
Fertility impairment	Estrogen therapy can lead to a reduction in spermatogenesis. Patients are counselled that treatment might affect their fertility and are offered sperm storage before starting treatment.
Liver dysfunction	LFT abnormalities are usually minor and do not require stopping treatment. An increase in liver enzymes to more than three times the upper limit of normal requires suspension of treatment; seek advice from the Welsh Gender Team.
Hyperprolactinaemia	Serum prolactin may rise with the introduction of estradiol therapy. If there is a new rise of > 750 mIU/L, repeat the test. If this test confirms the rise of >750mIU/L refer to the Welsh Gender Team. If there is a new rise of > 1,000 mIU/L, repeat the test and inform the Welsh Gender Team.
GnRH Agonists This treatment is well tolerated and generally not associated with significant side effects. The use of GnRH agonists in conjunction with cross-sex hormone therapy mitigates menopausal symptoms, cardiovascular risk and bone demineralisation. Some patients report short-lived musculoskeletal aching immediately after each injection which resolves after one or two days. Low energy, drive, or sexual desire should be reported to the Welsh Gender Team	
Finasteride For a comprehensive list (including rare and very rare adverse effects), or if significance of possible adverse event uncertain, consult the Summary of Product Characteristics or BNF.	

System	**Frequency**	**Reaction**
Immune system disorders	Not known	Hypersensitivity reactions, including pruritus, rash, urticarial and swelling of the lips and face
Cardiac disorders	Not known	Palpitations
Psychiatric disorders	Uncommon (≥1/1,000 to <1/100)	Decreased libido
	Uncommon (≥1/1,000 to <1/100)	Depressed mood
Hepatobiliary disorders	Not known	Increased hepatic enzymes

	Breast cancer	Not known	Breast cancer has been reported. Prompt reporting of changes in breast tissue is encouraged and uptake of the National Breast Screening program is strongly advised.
	PSA screening	Finasteride has been shown to reduce PSA levels and this should be taken into consideration if a patient requires PSA testing	
7. Baseline investigations	**To be undertaken by secondary care** Full blood count (FBC), liver function test (LFT), HbA1c*, fasting lipids, prolactin, luteinising hormone (LH), follicle-stimulating hormone (FSH), testosterone, estradiol, sex hormone-binding globulin (SHBG), and vitamin D. Renal function if indicated.		

	Monitoring	**Frequency**	**Results**	**Action**	**By**
8. Monitoring	**Testosterone: Gels** Record BP, BMI and smoking status at each monitoring visit				
	FBC **LFT** **Fasting lipids** **Testosterone**	10 weeks after start of treatment and after dose adjustment. When in range, every 3 months for 2 tests in range, then every 6 months for 2 tests in range Then ANNUAL Withdraw blood 4–6 hours after gel is applied. Advise the patient not to apply the gel to the arms or shoulders on the day of the test	**Testosterone target range 15-20nmol/L**	<15 nmol/L Local Gender Team to titrate dose. >20nmol/L GP to contact Local Gender Team	Local Gender Team GP
	Testosterone: Short-acting Injection (e.g. Sustanon®) Record BP, BMI and smoking status at each monitoring and administration visit				
	FBC **LFT** **Testosterone (Trough & Peak)**	Every 4th dose: take trough level morning before dose and then peak level a week later until in range. If remaining on short acting injection, then every 8th injection then ANNUAL	**Trough testosterone range 8-12nmol/L** **Peak testosterone range 25-30nmol/L**	Report trough>20nmol/L or peak > 40nmol/L to Local Gender Team to action	GP
	Testosterone: Long-acting Injection (e.g. Nebido®)				
	FBC **FBC** **LFT** **Fasting lipids** **Testosterone (Trough)**	Before 2nd and 3rd dose. Immediately (or up to 2 days) before 4th injection. Retest at 3rd injection after interval changed, confirm at next injection, next 2 alternate doses then ANNUAL	**Trough target range 15-20nmol/L**	Report trough <15nmol/L or > 25nmol/L to Local Gender Team action	GP
	Annual Blood Test				

	LFT **Prolactin** **Testosterone**[a] **Estradiol** **Fasting Lipids** **HbA_{1C}**[b]	[a] Not required if on Gn\rH agonist or prior orchidectomy [b] Request fasting glucose if patient has known haemoglobinopathy **And Record:** Blood pressure, BMI and smoking status	Results out of normal range	Contact Local Gender Team	GP
	Uterine trans-abdominal ultrasound scan (if uterus present)	Refer for scan every 2 years after staring testosterone treatment	Abnormalities reported	Contact Local Gender Team	GP

	Monitoring	Frequency	Results	Action	By
	Estrogen Record BP, BMI and smoking status at each monitoring visit				
	LFT **Prolactin** **Testosterone** **Estradiol**	10 weeks after initiation and every dose change until 2 consecutive tests are within range 3 months apart followed by 2 consecutive tests 6 months apart and then Annual Blood Test	**Target serum estradiol range 350-750 pmol/L** **Serum testosterone> 3 nmol/L**	< 350 or >750 pmol/L Titrate dose Contact Local Gender Team	Local Gender Team GP
	GnRH Agonists and Finasteride **As per estrogen**				
	Annual Blood Test				
	LFT **Prolactin** **Testosterone**[a] **Estradiol** **Fasting Lipids** **HbA_{1C}**[b]	Annual [a] Not required if on GnRH agonist or prior orchidectomy [b] Request fasting glucose if patient has known haemoglobinopathy **And Record:** Blood pressure, BMI and smoking status	Results out of normal range	Contact Local Gender Team	GP
9. Pharmaceutical aspects	No special considerations				
10. Advice to patients and carers The specialist will counsel the patient with regard to the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information	**Testosterone gel** Tostran® is required in higher volumes and so tends only to be used in the treatment of those non-binary individuals who require a bespoke low-dose arrangement. Tostran® can also be used as a short-term measure if other options are out-of-stock. The complete dose should be administered in one aliquot, and applied to the shoulders, arms or abdomen. Advise your patient to wash their hands with soap after each application, and to cover the area with clothing to avoid skin-to-skin transfer. Consult the Summary of Product Characteristics or Patient Information Leaflet for each product. Blood tests: Advise the patient not to apply the gel to the arms or shoulders on the day of the test. Withdraw blood 4–6 hours after gel is applied.			

leaflets on individual medicines	

11. Pregnancy (men and women) and breast feeding It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review but the ongoing responsibility for providing this advice rests with both the primary care prescriber and the specialist.	**Testosterone**	**Estrogen (Estradiol)**	**Gonadotrophin-releasing hormone(GnRH) agonists**	**Finasteride**
	Trans man or non-binary person with intact uterus: Notify the initiating consultant giving a comprehensive medication record including dates of administration of injections (if used). If patient is using testosterone gel, advise them to stop using the gel until they have been reviewed	If pregnancy occurs, treatment should be withdrawn immediately. The results of most epidemiological studies to date relevant to inadvertent foetal exposure to oestrogens indicate no teratogenic or foetotoxic effects.	GnRH agonists should not be used in pregnancy due to a theoretical risk of miscarriage or foetal abnormalities. Women who become pregnant while taking GnRH agonists should be referred to the Welsh Gender Team immediately.	People who become pregnant while taking finasteride should be referred to the Welsh Gender Team immediately because finasteride may cause abnormalities of the external genitalia of a male foetus.
12. Secondary care contact information	**HDUHB Local Gender Team**		**Welsh Gender Service**	

13. Criteria for shared care	If stopping medication or needing advice please contact: Dr Sam Rice, Consultant Endocrinologist Contact Email: Sam.rice@wales.nhs.uk Alternative Email: HDUHB.GMS@wales.nhs.uk For Out of Hours advice, please telephone: Medical Registrar on-call at local hospital	Mobile number for endocrine advice (11.30–14.30): 07971529080 Phone number for general enquiries: 02921 836612 Phone number for appointment enquiries: 02921 847548 Email for endocrine enquiries: cav.wgs@wales.nhs.uk Email for all other enquiries: cav.wgs_enquiries@wales.nhs.uk Address: Welsh Gender Service St David's Hospital Cowbridge Road East Cardiff CF11 9XB
	Prescribing responsibility will only be transferred when: • Treatment is for a specified indication and duration. • Treatment has been initiated and established by the secondary care specialist. • The patient's initial reaction to and progress on the drug is satisfactory. • The primary care prescriber has agreed in writing in each individual case that shared care is appropriate. • The patient's general physical, mental and social circumstances are such that he/she would benefit from shared care arrangements.	

14. Responsibilities of initiating consultant	• Initiate treatment. • Undertake baseline monitoring. • Dose adjustments. • Monitor patient's initial reaction to and progress on the drug. • Ensure that the patient is taking their medication and has an adequate supply of medication until primary care supply can be arranged. • Continue to monitor and supervise the patient according to this protocol, while the patient remains on this drug. Provide primary care prescriber with: • Diagnosis, relevant clinical information and baseline results, treatment to date and treatment plan, duration of treatment before consultant review. • Provide primary care prescriber with details of outpatient consultations, ideally within 14 days of seeing the patient, *or* inform primary care prescriber if the patient does not attend appointment. • Advice on when to stop this drug. Provide patient with relevant drug information to enable: • Informed consent to therapy. • Understanding of potential side effects and appropriate action. • Understanding of the role of monitoring. • Monitoring booklet where appropriate.

15. Responsibilities of primary care	• To monitor and prescribe in collaboration with the specialist, according to this protocol. • To ensure that the monitoring and dosage record is kept up to date. • Symptoms or results are appropriately actioned, recorded and communicated to secondary care when necessary. Provision of shared care is in accordance with Local Enhanced Scheme.
16. Responsibilities of patients	• To attend hospital and primary care appointments, including those for monitoring. • Ensure monitoring booklet (if issued) is taken to appointments. • Failure to attend will result in medication being stopped (on specialist advice). • To report adverse effects to their specialist or primary care prescriber.
17. Additional responsibilities	Responsibilities of all prescribers: Any serious reaction to an established drug should be reported to MHRA.
18. Supporting documentation	Include patient information leaflet if available
19. Patient monitoring booklet	Include patient information leaflet if available
20. Primary care letter	Attached below
References	SmPC Finasteride 1mg tablets Aurobindo Pharma-Milpharm Ltd. Date of Revision:15.6.2021. Updated on emc: 19.June 2020 (Accessed:12.05.2021) Finasteride 1mg tablets - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk) SmPC Nebido 1000mg/4ml, solution for injection. Bayer plc. Date of Revision: 2nd Mar 2020 Updated on emc: 6th Mar 2021 https://www.medicines.org.uk/emc/product/3873 SmPC Progynova 1mg tablets Bayer plc. Date of revision: 26 August 2020. Updated on emc: 02 Sept 2020. https://www.medicines.org.uk/emc/product/1415/smpc Testogel 16.2mg/g gel Besins Healthcare (UK) Ltd Date of Revision: 12 Feb 2021. Updated on emc: 02 Mar 2021https://www.medicines.org.uk/emc/product/8919/smpc SmPC Decapeptyl SR 11.25mg (triptorelin pamoate) Ipsen Ltd. Date of revision: 5 July 2017 Updated on emc:9.Aug 2017 https://www.medicines.org.uk/emc/product/780
21. Guideline date	May 2021
22. Guideline review date	May 2023

GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol Hywel Dda University Health Board

Flowchart of the monitoring requirements for TESTOSTERONE, ESTROGEN, GONADOTROPHIN-RELEASING HORMONE (GnRH) AGONISTS and FINASTERIDE THERAPY for ENDOCRINE MANAGEMENT OF GENDER DYSPHORIA IN ADULTS

Testosterone

Gel

Withdraw blood 4–6 hours after gel is applied. Advise the patient not to apply the gel to the arms or shoulders on the day of the test

Every 10 weeks
FBC LFT Fasting lipids
Testosterone
until 2 consecutive results are within range:
Testosterone target range 15-20nmol/L
Repeat 10 weeks after dose adjustment

Every 3 months
FBC LFT Fasting lipids
Testosterone
until 2 consecutive results are within range

Every 6 months
FBC LFT Fasting lipids
Testosterone
until 2 consecutive results are within range

Sustanon®

At each visit Record BP, BMI and smoking status

Morning before 4th Injection
(12 weeks from start)
FBC LFT Fasting lipids
Testosterone trough level
Week after 4th injection
Testosterone peak level
until 2 consecutive results are within range:
Trough testosterone range 8-12nmol/L
Peak testosterone range 25-30nmol/L

Morning before 8th Injection
FBC LFT Fasting lipids
Testosterone trough level
Week after 8th injection
Testosterone peak level
until 2 consecutive results are within range

Every 2 years after staring testosterone
Uterine trans-abdominal ultrasound scan (if uterus present)

Nebido®

Before 2nd and 3rd injection
FBC

Before 4th injection
(or up to 2 days before)
Testosterone Trough level target range 15-20nmol/L

Before 3rd injection after interval changed, retest and confirm testosterone trough is within range at and then **at next injection** then **next 2 alternate doses**

Estrogen **Finasteride**
Gonadotrophin-releasing hormone (GnRH) agonists

At each monitoring visit Record BP, BMI and smoking status

Every 10 weeks
LFT Prolactin Testosterone Estradiol
Until 2 consecutive results are within range
serum estradiol target range 350-750 pmol/L
Serum testosterone <3 nmol/L

Repeat 10 weeks after dose change or GnRA added

Every 6 months
LFT Prolactin Testosterone Estradiol
Until 2 consecutive results are within range

Annual Blood Test (and record: Blood pressure, BMI and smoking status)
LFT
Prolactin
Testosterone[a] [a] Not required if on Gn\rH agonist or prior orchidectomy
Estradiol
Fasting Lipids
HbA_{1C}[b] Request fasting glucose if patient has known haemoglobinopathy

SHARED CARE AGREEMENT FORM

Consultant request

Dear

IMPORTANT: ACTION NEEDED

Patient name:
Date of birth:
NHS number:
Diagnosis:

This patient is suitable for treatment with (*insert drug name*) for the treatment of *(insert indication).*

This drug has been accepted for Shared Care according to the enclosed protocol (as agreed by Trust/Health Board/AWMSG). **I am therefore requesting your agreement to share the care of this patient, as they are now stable on the treatment**. Where baseline investigations are set out in the shared care protocol, I have carried these out.

Treatment was started on (*insert date started*) (*insert dose*).

If you are in agreement, please undertake monitoring and treatment from *(insert date*). (NB: date must be at least 1 month from initiation of treatment.)

Baseline tests: ***(insert information)***

Next review with this department: *(insert date)*

You will be sent a written summary within (*XX)* days. The medical staff of the department are available at all times to give you advice. The patient will not be discharged from out-patient follow-up while taking *(insert drug name)*.

Please use the reply slip overleaf and return it as soon as possible.

Thank you.

Yours

Signature *Date*

Consultant name

GP RESPONSE

Dear

Patient: *(Insert Patient's name)*

Identifier: (Insert Patient date of birth/address/NHS number)

I have received your request for shared care of this patient who has been advised to start (*insert drug name):*

A I am willing to undertake shared care for this patient as set out in the protocol

B I wish to discuss this request with you

C I am unable to undertake shared care of this patient for the reason(s) below:

	Reason	Tick
1.	**A minimum duration of supply by the initiating physician** As the patient has not had the minimum supply of medication to be provided by the initiating specialist I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***Until the patient has had the appropriate length of supply the responsibility for providing the patient with their medication remains with you.***	
2.	**Initiation and stabilisation by the initiating specialist** As the patient has not been stabilised on this medication I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***Until the patient is stabilised on this medication the responsibility for providing the patient with their medication remains with you.***	
3.	**Shared Care Document not received** As legal responsibility for clinical care lies with the doctor who signs the prescription, I need to ensure that I am in possession of sufficient clinical information for me to be confident to prescribe this treatment for my patient and it is clear where each of our responsibilities lie to ensure the patient is safely managed. For this reason I am unable to take clinical responsibility for prescribing this medication at this time, therefore would you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***Until I receive this information, responsibility for providing the patient with their medication remains with you.***	
4.	**Other (Primary Care Prescriber to complete if there are other reasons why shared care cannot be accepted)**	

Signature of primary care prescriber Date

Contact details (phone number and email):
GP address/practice stamp