NHS
Pan Mersey
Area Prescribing Committee

Prescribing Support Information

TESTOSTERONE

to achieve masculinisation following assessment and diagnosis of Gender Incongruence at the NHS commissioned Cheshire and Merseyside Gender Identity Service

AMBER following specialist initiation

Your patient has been identified as being suitable to receive testosterone in accordance with the indications detailed below. They have been started on treatment and have been reviewed to assess the efficacy and adverse effects of the treatment by the specialist team. Prescribing has been retained by the specialist team for the first 6-12 months until stabilisation of the dose and monitoring requirements has been achieved. Testosterone treatment will be lifelong and will continue following any future surgery that may include gonadectomy.

Testosterone has been considered as appropriate for prescribing in primary care and the information contained in this document has been provided to support you to prescribe the medicine for your patient in the community. Your patient's dose is now stable and is detailed in the attached clinic letter.

Except for Sustanon®, these medicines are not licensed for the treatment of gender incongruence. However, they are medicines with which GPs may be familiar.

There has been a significant amount of experience in the treatment of gender incongruence over the last 40 years, using several well-established hormonal protocols, and 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.[1,2]

Your patient will not remain under the care of a specialist team within Cheshire and Merseyside Gender Identity Collaborative (CMAGIC) whilst receiving this medicine but will be able to be fast tracked back into the gender service if there are any issues.

Indication

To achieve amenorrhoea and physical masculinisation following assessment and diagnosis at CMAGIC.

Name of Drug, Form and Starting Dose

Sustanon® 250mg/ml solution for IM injection. 250mg every 3 weeks.

Long-acting testosterone depot injection:
Nebido® 1000 mg/4 ml, solution for IM injection (testosterone undecanoate). Initial injection to be followed by a second injection after 6 weeks and then at 12-week intervals.

Transdermal Testosterone Gel:
Testogel® 16.2mg/g gel. 20.25mg per metered dose. Starting dose, 2 actuations of the pump once a day. (Usual range 2-3 actuations).
Tostran® 2% gel, 10mg per metered dose from pump applicator. Starting dose, 4 actuations of the pump once a day. (Usual range 4-6 actuations).
Testavan® 20 mg/g Transdermal gel. 23mg per metered dose. Starting dose, 2 actuations of the pump once a day. (Usual range 2-3 actuations).

The target testosterone range is 15-20nmol/l.

Monitoring recommendations
The Gender Clinicians will carry out a full assessment of the patient's suitability for treatment and will carry out the following baseline blood screening:

Blood pressure, full blood count, liver function, fasting blood glucose or HbA1C, lipid profile, thyroid function, serum testosterone, oestradiol, prolactin, LH and FSH.

The following will be measured every 3-6 months until stable:

FBC, testosterone, haematocrit, liver function tests, fasting blood glucose and lipid profile.

Ongoing monitoring by GP practice:

Annually:
Testosterone, haematocrit, liver function tests, fasting blood glucose and lipid profile.

Injections, immediately prior to the administration of a scheduled injection.

For patients on a gel, the blood sample should be drawn 2-4 hours after gel application.

If menstruation returns once stabilised please check FSH, LH and oestradiol, and inform CMAGIC of the continued menstruation and test results.

Administration information
Testosterone injections are usually administered by the GP practice. Nebido® injections must be administered very slowly (over two minutes) by deep intramuscular injection. Some patients can be trained to self-administer Sustanon® injections.

Gel should be applied to the abdomen (entire dose over an area of at least 10 by 30 cm), or to **both** inner thighs (one half of the dose over an area of at least 10 by 15 cm for each inner thigh). Daily rotation between the abdomen and inner thighs is recommended to minimise application site reactions.

Contra-indications

- Known hypersensitivity to the active substances or to any of the excipients.
- Known or suspected carcinoma of the breast or the prostate.

Special warnings, cautions, adverse effects, and interactions with other medicines
For a comprehensive list, consult the BNF or Summary of Product Characteristics.

Criteria for stopping treatment (GP or specialist)
Significant side effects / lack of response at adequate doses / client self-discharges from CMAGIC.

Follow up arrangements

Gender Clinicians:
The CMAGIC clinical team will provide training, support and advice for GPs, Community Pharmacists and District Nurses on request. Patients will be reviewed by CMAGIC at regular intervals. Audit of patients' blood results can occur remotely to support ongoing care.

GP:
The primary care team will be responsible for the ongoing prescribing of gonadorelin analogues and testosterone and will continue to act as the primary contact for general healthcare.

GP/Primary Care to refer back to the specialist team if any significant developments or deterioration occur, such as occurrence of side-effects or complications of hormone therapy.

Other information
Patients are given a copy of the consent agreement when starting therapy, it contains the disclosure of risks, benefits, and management plan. It is also available for GPs by contacting the service on cmagic.merseycare@nhs.net or by writing to the clinic to request a copy. It is based on The Practical Management of Hormonal Treatment in Adults with Gender Dysphoria[3]**.**

The specialist team will take responsibility for the initiation of treatment, counselling about risks and benefits of therapy, and ongoing responsibility for making alterations to therapy until the patient is stabilized.

- To oversee the whole programme of assessment and treatment, including dose adjustment as necessary to reach a maintenance level.
- To liaise with the GP on arrangements for stopping medication prior to any elective surgery, and restarting it afterwards
- To advise GP on any problems arising from this treatment which may need a dose adjustment or a change in medication or formulation.

Contact details for advice

CMAGIC
Sexual Health/Abacus
6 David Lewis Street
Liverpool
L1 4AP
Tel: 0151 317 8581
cmagic.merseycare@nhs.net

References

1. Gooren, L. J., van de Wall, H. A. D. (2007). Hormone treatment of adult and juvenile transsexual patients. In R. Ettner., S. Monstrey and A. E. Tyler (Eds.), Principles of Transgender Medicine and Surgery (pp 73-88). New York: The Haworth Press.
2. Seal, L.J. The practical management of hormonal treatment in adults with gender dysphoria. In: J Barrett, editor. Transsexual and Other Disorders of Gender Identity: a practical guide to management. Oxford: Radcliffe; 2007. 157-190.
3. Barrett, J. Transsexual and other disorders of Gender Identity a practical guide to management. 2007 Oxford Press

Acknowledgements

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SPECIALIST GENDER IDENTITY CLINIC TEAM / CONSULTANT RESPONSIBILITIES

- Establish or confirm diagnosis and assess patient suitability for treatment
- Baseline monitoring of bloods by GIC Endocrine Team
- 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.
- Obtain signed consent for hormonal treatment.
- Monitor treatment according to clinical guidance and carry out dose titration of medicines.
- Send prescribing support information and a signed patient letter with patient details completed together with relevant clinical information to GP for consideration of request to prescribe.
- Contact GP directly if response to request has not been received within 2 weeks

Ongoing Care Arrangements: Specialist team to

- Write to GP following clinic contacts
- Inform GP of abnormal monitoring results and any recommended 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
- Make arrangements for ongoing monitoring and follow up, including continued need for therapy.

Consultant/Gender Specialist Nurse:
The CMAGIC clinical team will provide training, support and advice for General Practitioners, Community Pharmacists, District Nurses, on request.

GP RESPONSIBILITIES

- Prescribe treatment as advised by the Specialist Team and previously discussed with the patient
- Monitor general health of patient and check for adverse effects as appropriate
- Inform specialist consultant of suspected adverse effects
- Stop treatment on advice of Gender Clinician or immediately if urgent need arises
- Check compatibility interactions when prescribing new or stopping existing medication
- Carry out monitoring and follow up according to prescribing support information
- Discuss any abnormal results with Gender Clinician/specialist team and agree any action required

PATIENT'S RESPONSIBILITIES

- Keep a copy of information provided by Gender Identity Clinic, including consent to treatment, to take along when seeing your GP
- Take medicines as agreed and prescribed
- Report any adverse effects to GP or Gender Clinician at the earliest opportunity
- Ensure that you attend for monitoring as requested by your Gender Clinician or GP
- Do not share medicines with other individuals
- Attend appointments for review as necessary
- Always inform the Specialist team and GP of all medication being taken, whether prescribed or bought

Appendix 1 GP Letter

GENDER CLINICIAN

I confirm that I have assessed the patient today,

Attach patient addressograph or
Insert patient details

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 “ongoing care arrangements”.

Signature:

Print Name:

Date: