NHS
Pan Mersey
Area Prescribing Committee

Prescribing Support Information

OESTROGEN THERAPY

to achieve feminisation 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 oestrogen 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 have been achieved. Oestrogen treatment will be lifelong and will continue following any future surgery that may include gonadectomy.

Oestrogen 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.

The standardised mortality rate for transgender and non-binary people (TGNB) is 1.0, demonstrating that longer term oestrogen therapy is not detrimental or harmful. This means that patients are no more likely to die as a result of taking this treatment than if it was not prescribed at all.

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]

Although these medicines are not licensed for the treatment of gender incongruence, they are medicines with which GPs may be familiar. The doses of oestrogen are often slightly higher than would be prescribed in those who are assigned female at birth as those assigned male often have a large muscle mass and therefore require a larger dose to reach an adequate physiological dose.

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 feminisation and the suppression of testosterone levels following diagnosis and assessment at CMAGIC.

Name of Drug, Form and Dose

First line:

Transdermal gel or spray estradiol (Sandrena®, Oestrogel® or Lenzetto®) 1-5mg/day:
Dose titrated 3-monthly, to achieve plasma estradiol levels of 400-600pmol/l, 4-6 hours after application to the skin.

Second line:

Estradiol patches 100–200mcg applied twice weekly.
Dose titrated 3-monthly to achieve plasma estradiol levels of 400-600pmol/l, 48 hours after the patch is applied to the skin.

Third line:

Estradiol valerate initiated at a dose of 2mg bd, orally, and used in a range of 4-10mg daily:
Dose titrated 3-monthly, to achieve plasma estradiol levels of 400-600pmol/l, 4-6 hours after taking the tablets.

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:

LH, FSH, testosterone, estradiol, sex hormone binding globulin (SHBG), prolactin, PSA, fasting lipid profile, LFTs, HbA1c, Vitamin D, and renal function. Weight, height, BMI, and blood pressure (from GP records if available).

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

Testosterone levels until stable (range 0-3 nmol/l)
Estradiol blood level (range 400-600pmol/l),
Prolactin, LFTs, fasting lipids, HbA1c, weight, height, blood pressure.

Ongoing monitoring by GP practice:

Annually:
Estradiol blood level (range 400-600pmol/l),
Prolactin, LFTs, fasting lipids, HbA1c, weight, height, blood pressure.

Contra-indications

- Known hypersensitivity to the active substances or to any of the excipients.
- Acute liver disease, or a history of liver disease when liver function tests have failed to return to normal.

For a full list, consult the BNF or Summary of Product Characteristics.
Although previous VTE is listed as a contraindication in all the oestrogen SPCs, there is robust evidence that this would not apply to transdermal oestrogen[3].

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.
- Review dosage and/or formulation if the patient starts smoking.
- Development of significant contraindication to oestrogen use.

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 (or a locally commissioned GP with specialist interest) will be responsible for the ongoing prescribing of oestrogens and will continue to act as the primary contact for general healthcare.

GP/Primary Care clinician to refer back to the specialist team if any significant developments or deterioration occur, such as occurrence of side-effects, or complications of feminising hormone therapy, such as venous thromboembolic disease, gallstones, elevated liver enzymes, hyperprolactinaemia, significant weight gain or hypertriglyceridemia.

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[4]**.**

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 stabilised.

- 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. 157-19
3. Vinogradova Y et al. Use of hormone replacement therapy and risk of venous thromboembolism: nested case-control studies using the QResearch and CPRD databases. BMJ 2019;364:k4810. BMJ
4. Barrett, J. Transsexual and other disorders of Gender Identity a practical guide to management. 2007 Oxford Press

Acknowledgements
This document was adapted from the Tavistock and Portman adult GIC guidance, which was prepared by Dr Leighton Seal, Consultant Endocrinologist, Charing Cross GIC, the CXGIC Clinical Team and WLMHT Chief Pharmacist.

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: