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| ***Prescribing Information*** | **Oestrogel : Amber Drug Guidance for Gender Dysphoria in** **Adults****Amber Drug Level 3** (amber drug with monitoring requirements)**Amber Level 3** ‘Medicines that should be initiated by a specialist, and which require significant monitoring on an ongoing basis.  These medicines are considered suitable for GP prescribing (which may include titration of dose). After a successful initiation period and assessment of efficacy, a transition to GP care can take place.  Full agreement to share the care of each specific patient must be reached under the amber drug agreement, and amber drug guidance must be provided to the GP (available on LHP).  We have started your patient on Oestrogel for the treatment of gender dysphoria. We will continue to see the patient and prescribe Oestrogel until the patient (and their condition) is stable (minimum period of 12 weeks). After this period the GP will be asked to take over prescribing and monitoring responsibilities within this amber drug protocol. **This drug requires ongoing monitoring which does include blood tests.**This guideline outlines the specific responsibilities of the Specialist, GP, and patient when Oestrogel is prescribed.**The following is a summary of prescribing information only.** **Consult the** [**BNF**](https://www.medicinescomplete.com/mc/bnf/current/) **and** [**SPC**](https://www.medicines.org.uk/emc/browse-medicines) **for full and current prescribing information.**The link to Oestrogel on the Leeds formulary can be found [here](http://www.leedsformulary.nhs.uk/chaptersSubDetails.asp?FormularySectionID=6&SubSectionRef=06.04.01.01&SubSectionID=A100&drugmatch=531#531).**Indication for therapy:** The initiation of Oestrogel in adults is outside of the product licence i.e. an unlicensed indication. However, this indication is fully supported by The World Professional Association for Transgender Health (WPATH) and the patient has given informed consent.  **Classification:** Amber Level 3**Monitoring:** Required**Baseline Tests: Required prior to any treatment by specialist from GP**Specialist to inform GP in a clinic letter what tests need doing. Patients will attend the GP for the following blood tests, the results of which will be required for all hormone appointments with the specialist: * Pre-screen for breast and prostate cancer (PSA) prior to beginning treatment. Do PSA and examination of prostate if required.
* Blood pressure
* U&Es
* FBC
* Calcium
* LFTs
* TFTs
* HbA1c
* Fasting full lipid profile including fasting triglycerides and cholesterol
* Prolactin - preferable done as first thing in the morning before a meal
* Testosterone
* Estradiol/oestradiol
* FSH
* LH
* Sex hormone binding globulin (SHBG)
* DEXA scan for patients at risk of osteoporosis as per local/NICE guidance

**Routine Tests/Monitoring:** **During the stabilisation period,** patients will attend the GP for the following blood tests (usually 3-6 monthly) as advised by the specialist. The results will be required for all hormone appointments at the clinic with the specialist. These can be sent with the patient to the appointment or email them to the gender service at gid.lypft@nhs.netUpon transfer to the GP the following should be measured 6 monthly for the first year and then annually thereafter:* LFTs – refer to specialist if greater than 3 times the normal upper limit and stop treatment;
* Prolactin – refer to specialist if greater than 1000miu/L;
* HbA1c - treat as high risk of diabetes or diabetes pathway if raised;
* Full lipid profile – treat as per local hypercholestaemia guidance; and calculate QRISK score as appropriate;
* Estradiol/oestradiol target range: 350-750 pmol/L; for those over 40 years of age consider a lower range of 300-600 pmol/L and over 50 years 200-400 pmol/L, refer to gender identity service specialist if out of range in first 12 months or local endocrinology service after 12 months;
* Testosterone refer to specialist if greater than normal male reference range for individuals prescribed an oral anti-androgen or GnRH agonist (e.g. Leuprorelin) or if testosterone levels fail to be suppressed by GnRH agonist treatment;
* FSH or LH – refer to specialist if persistently elevated despite estradiol/oestrodiol level within the target range.

**Bloods tests required once stable and staying on hormones or awaiting surgery:****Do blood tests 6 monthly for the first year then annually unless otherwise stated in letter from the Gender Identity Service.*** LFTs – refer to specialist if greater than 3 times the normal upper limit and stop treatment;
* Prolactin – refer to specialist if greater than 1000miu/L;
* HbA1c – treat as high risk of diabetes or diabetes pathway if raised;
* Full lipid profile – treat as per local hypercholestaemia guidance; and calculate QRISK score as appropriate;
* Estradiol/oestradiol target range: 350-750 pmol/L; for those over 40 years of age consider a lower range of 300-600 pmol/L and over 50 years 200-400 pmol/L, refer to (check which service) specialist if out of range – first 12 months Gender Identity service or after 1 year the local endocrinology service;
* Testosterone refer to specialist if greater than normal male reference range for individuals prescribed an oral anti-androgen or GnRH agonist (e.g. Leuprorelin) or if testosterone levels are fail to be suppressed by GnRH agonist treatment;
* FSH or LH – refer to specialist if persistently elevated despite estradiol/oestrodiol level within the target range.
* Stop treatment immediately if any of the following develop and discuss with specialist DVT/PE;
* Any deterioration or 3 x upper in liver function.

Treatment may be restarted if anticoagulated or if liver function improves after discussion with gender identity service specialistDiscuss with specialist if:* Blood pressure increases to hypertensive range (BP ≥140/90);
* New onset of migraine-type headache.

**Disease Monitoring:** Estradiol/oestradiol (dependent on age and previous medical history) and Testosterone levels act as a marker for hormone reassignment and the GP will be asked to have the blood results available for follow-up appointments.NB: Some individuals may fall outside the above reference ranges, but this will be detailed in correspondence from the specialist to the GP.**Follow up:** **Patients progressing to gender reassignment surgery.** Stable patients – Transferred to the GP, and will be seen for post-op appointment and when stable will be discharged to the GP. If any concerns write to specialist or refer back to the Gender Identity Service**Patient for hormone reassignment only** Stable patients – discharged to GP. If any concerns write to specialist or refer back to the Gender Identity Service**Follow up:**See clinic letter**Dose: ONE or TWO metered doses DAILY**, according to individual requirement. See clinic referral letter for recommended dose for individual patients. The following information has been added only if it differs from the BNF and SPC or supports that information.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| ***Communication*** | **Contact Names and Details****Leeds and York Partnership Foundation Trust** Leeds Pharmacy phone number and e-mail: **0113 85 56393** Pharmacyleedspft.lypft@nhs.net Gender identity Service - gid.lypft@nhs.netPatient information leaflets: [www.choiceandmedication.org/leedsandyorkpft](http://www.choiceandmedication.org/leedsandyorkpft)**Prepared by:** Caroline Dada, Lead Pharmacist, LYPFT Dr Peter Hammond, Consultant Endocrinologist\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| ***Declarations of Interest*** | **Declarations of Interest by authors**All (or any) declarations of interest were declared and considered, through the appropriate process.Contributors are to declare any changes to their declaration of interest submission within 28 days.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| ***Responsibilities of Specialist*** | **Responsibilities Specific to Oestrogel for the treatment of Hormonal Gender Reassignment*** To discuss the diagnosis and ensure other treatment options have been fully explored and agreed with the patient
* To assess the suitability of the patient for this treatment
* To discuss the benefits and side effects/risks of treatment with the patient/carer and where applicable the need for long term monitoring
* To check the allergy status, drug interactions and contra-indications
* Baseline tests – requested from GP by specialist
* To initiate treatment
* To discuss with the patient the licensing issues with the Oestrogel for this indication and obtain written consent prior to initiating treatment.
* To assess and monitor the patients response to treatment until stable
* To ask the GP whether they are willing to take over the prescribing and monitoring responsibilities under this amber drug guidance
* To advise the GP on dose to be prescribed
* To advise GP what routine monitoring will be completed and what monitoring the GP will be responsible for
* To inform the GP of monitoring results required
* To outline to the GP when therapy may be reduced, discontinued or changed, minimising any relapse or deterioration in the patient’s condition. Review periods to be agreed
* To respond to issues raised by the GP
* To monitor the patient for adverse events and report to the GP and where appropriate Commission on Human Medicines/MHRA (Yellow card scheme)
* To review the patient in clinic at least every 3-6 months until stable
* To monitor weight & BMI
* Measure Blood pressure at each appointment

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| ***Responsibilities of GP*** | * To check for allergies
* To ensure there are no drug interactions and contra-indications with any other medications initiated in primary care or conditions developed in primary care
* To ensure all required monitoring is up to date before prescribing
* To prescribe Oestrogel and adjust the dose as recommended by the specialist following initiation and stabilisation by the specialist. Requires long term monitoring; if results outside of range, discuss with specialist
* To continue a maintenance prescription for Oestrogel until the patient progresses to surgery as advised by the specialist
* To perform routine monitoring as agreed with specialist
* To refer back to the specialist if the patient’s condition deteriorates
* To identify adverse events if the patient presents with any signs and symptoms and liaise with the hospital specialist where necessary. To report adverse events to the specialist and where appropriate the Commission on Human Medicines/MHRA (Yellow card scheme)
* To stop treatment on the advice of the specialist

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| ***Responsibilities of Patient/Carer*** | * To take responsibility for applying Oestrogel as prescribed.
* To attend for blood tests/disease monitoring on time.
* To understand potential for adverse events and report these to the Specialist and/or GP.
* To check with the community pharmacist that there are no drug interactions with Oestrogel, when buying any over the counter medicines or herbal/homoeopathic products.
* To check with dentists or other specialists who may prescribe medicines that there are no drug interactions with Oestrogel.
* To contact the GP, Specialist or Medicines Information patient helpline if further information or advice is needed about Oestrogel.

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