Hormone Therapy in Gender Dysphoria

AMBER0

Prescribing for **trans men** (this applies to a person assigned female, cis-female, at birth undertaking gender transition to become a male)

Prescribing Information Sheet: To be read in conjunction with the relevant SPCs

NHS England (NHSE) commission specialist gender identity centres. NHSE have stated that the patient's GP is responsible for organising blood and other diagnostic tests and for prescribing pharmacological treatments as recommended by the specialist identity centres. Therefore, it is likely that GPs will be requested to prescribe hormones for patients that are under the care of a specialist identity centre.

However, **NHSE has also stated that GICs should retain responsibility for providing prescriptions and for monitoring until the GP has agreed to a transfer of responsibilities. Individual prescribers MUST only prescribe within their own level of competence.**

The General Medical Council (GMC) have put together a set of ethical guidance on trans healthcare which can be accessed via: https://www.gmc-uk.org/ethical-guidance/ethical-hub/trans-healthcare. A summary of the main points follows:

- GPs can prescribe unlicensed medicines following the steps set out in GMC guidance
- If a patient is self-medicating with hormones that have been purchased, consider issuing a bridging prescription as part of a harm reduction approach. Seek the advice of an experienced gender specialist.

The following tables contain information relating to the most commonly requested hormone replacement therapies. **This information relates to trans men (a person assigned female, cis-female, at birth undertaking gender transition to become a male) only**. There is a separate prescribing sheet available for trans women (a person assigned male, cis-male, at birth undertaking gender transition to become a female) available on the LMMG website via www.lancsmmg.nhs.uk.

Table 1. Preparations for trans men (this applies to a person assigned female, cis-female, at birth undertaking gender transition to become a male)

Medication	**Typical Dosing and Product Information** off label use	**Additional Information** (See table 3 and 4 for Side Effects and Interactions)
Testosterone PC	Testogel® 50mg/5g sachets – Apply 50 to 100mg daily Tostran® 10mg/0.5ml pump – Apply 30 to 80mg daily	Apply to clean dry skin Apply to clean dry skin; one pump application = 10mg testosterone. CD Sch. 4. Life-long therapy.
Testosterone decanoate, isocaproate, phenylpropionate and propionate IM	Sustanon® 250 – 1ml every TWO to SIX weeks	Can be considered for self - administration. Contains peanut oil. CD Sch. 4. Life-long therapy.
Testosterone enantate IM	Generic – 1ml every TWO to SIX weeks	Can be considered for self - administration. CD Sch. 4. Life-long therapy.
Testosterone undecanoate IM	Nebido® 1g/4ml – 250 to 1000mg every 10 – 20weeks	**Not** suitable for self-administration. Steady-state reached after third dose – take blood for trough level just before administration of fourth dose. CD Sch. 4. Life-long therapy.
Leuprorelin acetate SC or IM	Prostap® SR DCS or Prostap® 3 DCS – 3.75 to 11.25mg every ONE, TWO or THREE months (as advised by the specialist centre).	Can be considered for self - administration. Typically used for refractory uterine bleeding.
Triptorelin IM Triptorelin acetate SC or IM	Decapeptyl SR 11.25mg Salvacyl 11.25mg Decapeptyl SR 3mg Gonapeptyl Depot 3.75mg 3 to 11.25mg every ONE, TWO or THREE months (as advised by the specialist centre)	**Not** suitable for self-administration. Typically used for refractory uterine bleeding.

Table 2. Dose adjustment of testosterone therapy. Seek further advice from the patient's original gender identity clinic if unable to achieve level in the therapeutic range.

Dose titration of testosterone gel preparations: Testogel®: if the testosterone level (taken 4 – 6 hours after application) >20nmol/L reduce dose by (25mg) ½ a sachet daily. If the testosterone level is <15nmol/L increase dose by 50mg (ONE sachet) daily. In both cases recheck levels in EIGHT weeks. **Tosteran®:** if the testosterone level (taken 4 – 6 hours after application) >20nmol/L reduce dose by 10mg (ONE pump) daily. If the testosterone level is <15nmol/L increase dose by 10mg (ONE pump) daily. In both cases recheck levels in EIGHT weeks.

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Dose titration of testosterone injectable preparations: if the trough testosterone level (taken immediately before the last dose) is >12nmol/L decrease the frequency of injections e.g. if receiving every THREE weeks reduce to every FOUR weeks. If the trough testosterone level is <8nmol/L increase the frequency of injection (e.g. if receiving every THREE weeks increase to every TWO weeks. In both cases recheck levels in THREE months.

Table 3. Monitoring and review requirements

The following tests or measurements should be monitored in primary care every SIX months for THREE years after starting hormone therapy and continued ONCE yearly thereafter.

Test or Measurement	Recommended action if the result is outside of the normal range
Body Mass Index	Manage according to local guidelines if BMI increases to over 30 – only necessary in this context if the patient is considering surgery.
Blood pressure	Manage according to local guidelines if BP greater than 140/90mmHg.
Haemoglobin and haematocrit	If a patient becomes significantly polycythaemic (haemoglobin > 175g/L or haematocrit >0.52 or 52%) or experiences a thrombotic event, testosterone treatment be should temporarily suspended and a haematology referral made – seek further advice from the patient's original gender identity clinic.
Urea and electrolytes	If out-of-range, seek further advice from the patient's original gender identity clinic.
Liver function tests	If elevated, refer to gastroenterology – seek further advice from the patient's original gender identity clinic.
HbA1c	If elevated, manage according to local guidelines.
Lipid profile	If elevated, manage according to local guidelines.
Serum testosterone	Serum testosterone should be at the lower end of the normal range. Measure trough level for injectables (trough range **< 8 – 12 nmol\L**; peak range **25 – 30nmol/L**). Take sample to measure levels for gel preparations 4 – 6 hours after application (**target is 17 – 18nmol/L**; range **15 – 20nmol/L).**
Serum estradiol	Target range **< 70pmol/L**; Seek advice from the patient's original gender identity clinic.
Serum prolactin	Target range **< 400mU/L**; Seek advice from the patient's original gender identity clinic.

Table 4. Summary of medication side effects Please refer to the individual medications SPC for more details

Testosterone

Likely increased risk

Polycythaemia*(see below for further details)
Weight gain
Acne
Androgenic alopecia (balding)
Sleep apnoea

Possible increased risk

Altered lipid profiles ** Liver dysfunction

Possible increased risk with presence of additional risk factors

Type 2 diabetes** Hypertension**
Mania and psychosis in patients with pre-existing disorders*
Cardiovascular disease

No increased risk or inconclusive

Breast Cancer, Osteoporosis, Cervical cancer, Ovarian cancer, Uterine cancer

*Risk is greater with supraphysiologic (beyond normal male range) serum levels of testosterone, which are more likely to be found with extended intramuscular dosing, than transdermal administration

**Patients with Polycystic Ovarian Syndrome may be at greater risk

Leuprorelin

Common or very common

Appetite decreased; arthralgia; bone pain; breast abnormalities; depression; dizziness; fatigue; gynaecomastia; headache; hepatic disorders; hot flush; hyperhidrosis; injection site necrosis; insomnia; mood altered; muscle weakness; nausea; paraesthesia; peripheral oedema; sexual dysfunction; testicular atrophy; vulvovaginal dryness; weight change

Uncommon

Alopecia; diarrhoea; fever; myalgia; palpitations; visual impairment; vomiting

Rare or very rare

Haemorrhage

Frequency not known

Anaemia; glucose tolerance impaired; hypertension; hypotension; leucopenia; paralysis; pulmonary embolism; QT interval prolongation; seizure; spinal fracture; thrombocytopenia; urinary tract obstruction

Triptorelin

Common or very common

Table 5. Interactions Please refer to the individual medications SPC for more details

Testosterone Testosterone can enhance the blood glucose-lowering effects of insulin. Increased anticoagulant effects and bleeding have been seen in patients taking a coumarin and an anabolic steroid or testosterone. **Leuprorelin and Triptorelin** The concomitant use of leuprorelin or triptorelin with medicinal products known to prolong the QT interval or medicinal products able to induce Torsade de pointes such as class IA (e.g. quinidine, disopyramide) or class III (e.g. amiodarone, sotalol, dofetilide, ibutilide) antiarrhythmic medicinal products, methadone, moxifloxacin, antipsychotics, etc. should be carefully evaluated. **Triptorelin** Drugs which raise prolactin levels should not be prescribed concomitantly as they reduce the level of GnRH receptors in the pituitary. When triptorelin is co-administered with drugs affecting pituitary secretion of gonadotropins, caution should be exercised and it is recommended that the patient's hormonal status be supervised.	Asthenia; depression; dizziness; dysuria; gastrointestinal discomfort; gynaecomastia; haemorrhage; headache; hot flush; hyperhidrosis; hypersensitivity; joint disorders; menstrual cycle irregularities; mood altered; muscle complaints; nausea; oedema; ovarian and fallopian tube disorders; pain; painful sexual intercourse; paraesthesia; pelvic pain; sexual dysfunction; sleep disorders; vulvovaginal dryness **Uncommon** Alopecia; appetite abnormal; asthma exacerbated; breast pain; chills; constipation; diarrhoea; drowsiness; dry mouth; dyspnoea; embolism; gout; hypertension; muscle weakness; skin reactions; testicular disorders; tinnitus; vision disorders; vomiting; weight changes **Rare or very rare** Abnormal sensation in eye; chest pain; confusion; diabetes mellitus; difficulty standing; fever; flatulence; hypotension; influenza like illness; memory loss; musculoskeletal stiffness; nasopharyngitis; orthopnoea; osteoarthritis; taste altered; vertigo **Frequency not known** Angioedema; anxiety; bone disorder; malaise; QT interval prolongation

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Please access this guidance via the LMMG website to ensure that the correct version is in use.

Version Control

Version Number	Date	Amendments Made
Version 1.0	July 2019	New guideline. AG.
Version 1.1	March 2021	Prescribing responsibility updated. AG.

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