Masculinising hormone treatment for trans men and non-binary people: Information for primary care professionals

Introduction

The following information has been produced by the Nottingham Centre for Transgender Health (NCTH) and is designed to inform healthcare professionals of the recommended hormonal treatment for trans and non-binary people.

The NCTH is a national service which carries out assessments to determine eligibility and readiness for hormone treatments amongst other functions. Once hormone treatment has been recommended the patient is guided through an information sheet to enable them to give informed consent. NCTH is not commissioned by NHS England to do blood monitoring, prescribe or administer hormone treatment. NCTH aims to work collaboratively with primary care teams in England to offer support and advice to GP's and their patients.

Primary care responsibilities-GMC guidance

The General Medical Council 2018 have online ethical guidance for General Practitioners for treating adult patients who are trans and non-binary. This guidance states:

> "GPs must co-operate with GICs (Gender Identity Clinics) and gender specialists in the same way as they would other specialists, collaborating with them to provide effective and timely treatment for trans and non-binary people. This includes:
> - prescribing medicines recommended by a gender specialist for the treatment of gender dysphoria
> - following recommendations for safety and treatment monitoring
> - making referrals to NHS services that have been recommended by a specialist."

With regard to the prescribing of off licence medication

> "Most of the medications used for the treatment of gender dysphoria are not licensed for this specific indication, although GPs will be familiar with their use in primary care for other purposes."

Further information can be found at https://www.gmc-uk.org/ethical-guidance/ethical-hub/trans-healthcare#prescribing

Initiating Masculinising Hormone Treatment

NCTH Responsibilities

It is the NCTH's responsibility to carry out the following:

- Assess for a diagnosis of gender dysphoria
- Discuss hormonal treatments including likely effects, risks and impact on fertility
- Assess for readiness for hormonal treatments
- Provide guidance to GP's in relation to baseline blood and blood pressure, height and weight monitoring before commencing hormonal treatment
- Review baseline blood monitoring
- Arrange an endocrinology review within the clinic for those patients with significant physical health issues or significant abnormalities in baseline blood results
- Send an information sheet about masculinising hormone treatment which has been signed by the patient and a clinician in the clinic with advice to the GP to start hormones including advice on the preparation and dose
- Review of the patient every 3 to 4 months
- Advise to the GP on preparation changes and dose adjustments as well as ongoing monitoring required
- Provide endocrinological advice to the GP regarding adverse effects if they come to the attention of the GP.

A copy of the information about masculinising hormone treatment sheet is attached as Appendix 1.

The usual baseline blood tests are as follows:

FBC, U&E's, LFT's, Lipid profile, Prolactin, Oestradiol, Testosterone, SHBG, LH, FSH and Glucose. These baseline bloods should be sent to the NCTH to be reviewed.

GP responsibilities

NCTH works collaboratively with GP's and will request GP's to do the following:

- Baseline blood monitoring. It is also recommended to record blood pressure, height and weight and to send copies of all the results to the NCTH
- Refer to local fertility services and request funding for gamete storage from the local CCG for those patients who wish to preserve their fertility prior to hormone treatment. Gamete storage is not funded through gender services which are themselves funded nationally via NHS England
- Prescribe hormone treatments as advised by NCTH
- Arrange blood monitoring as advised by NCTH and send copies of the results to NCTH.

Patient Responsibilities

Without safe monitoring of hormone therapy we may no longer support the prescribing of hormone therapy. We will require patients on hormone treatments to do the following:

- To attend review appointments every 3 to 4 months
- To attend for blood monitoring
- To be alert for and report any adverse effects e.g., polycythaemia.

Hormone regimens used

The hormone regimens that we commonly use in the initiation phase are summarised in Table 1.

Ongoing Masculinising Hormone Treatment

Once satisfactory testosterone levels have been achieved the blood monitoring required is set out in Table 2. Once treatment is established and other treatments such as surgeries, speech and language therapy, and psychotherapy are complete, patients are discharged from NCTH.

The GMC advocates "Once the patient has been discharged by a GIC or gender specialist, the prescribing and monitoring of hormone therapy can be carried out in primary care without specialist input. From the patient's perspective, management in primary care is far easier, and there is no specific expertise necessary to prescribe for and monitor patients on hormone therapy."

Once patients are discharged, a re-referral to a specialist team can be made if it is felt that the patient is experiencing distress or difficulties in adjustment in relation to their gender or treatment, regret, or adverse effects of hormone treatment.

Information about national NHS screening Programmes for transgender and non-binary people can be found at: www.gov.uk/government/publications/nhs-population-screening-information-for-transgender-people

Table 1: Testosterone therapy Initiation

	Dose range	Monitoring	Target	Safety
Gel Tostran pump (1 actuation = 10mg) Testogel pump (1 actuation = 20.25mg) Other options remain available but less flexible dosing; Testogel (50mg/sachet)	Start 40 mg daily and titrate monthly depending on blood results Dose range 50-100mg daily (Note: greater flexibility with dose titration using Tostran pump)	Monthly sampling 4-6 hrs **after** gel application *(early afternoon typically)*	Upper ½ of local reference range	**Before each dose titration** Testosterone FBC LFT
Sustanon If switching from gel stop gel with 1st injection	250 mg every 4 weeks	Trough level before 4th injection If dose interval changed repeat trough level after 3 further injections	Lower 1/3 of local reference range *If lower reduce injection interval* *If higher increase injection interval*	**Before each injection interval change** Testosterone FBC LFT
Nebido If switching from gel – continue gel for 1 week after 1st injection If switching from Sustanon, give Nebido instead of Susanton and continue with standard Nebido loading regimen	1000 mg stat 1000 mg at 6 weeks 1000 mg at 18 weeks 12 weekly thereafter	Sample at 6 mth (steady state) (26 weeks) *and ideally* Trough level before 4th injection (30 weeks) *Pragmatic recommendation based on large clinic catchment area and desirability of timely reviewing of faxed results*	Male reference range Lower 1/3 of local reference range *If lower reduce injection interval* *If higher increase injection interval*	**3 months** FBC LFT **6 months** Testosterone FBC LFT

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Adapted from: Hembree, W. C., Cohen-Kettenis, P. T., Gooren, L., Hannema, S. E., Meyer, W. J., Murad, M. H., T'Sjoen, G. (2017). Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society* Clinical Practice Guideline. Journal of Clinical Endocrinology & Metabolism. doi: 10.1210/jc.2017-01658

Table 2: Testosterone Steady State

	Dose range	Monitoring	Target range	Safety
Gel Tostran pump (1 actuation = 10mg) Testogel pump (1 actuation = 20.25mg) Other options remain available but less flexible dosing; Testogel (50mg/sachet)	Typical dose range is 50-100 mg daily 1-2 sachet daily (50 mg or 100 mg daily) limited dose adjustment	Sample 4-6 hrs **after** gel application *(early afternoon typically)*	Upper ½ of local reference range Monitor 2-3 times per year	**2-3 per yr** Testosterone **Annual** FBC LFT Lipids
Sustanon	250 mg every 2-4 weeks	Sample prior to next planned injection – trough level *Option to blood test 5-7 days after injection to check peak level.*	Lower 1/3 of local reference range *If lower reduce injection interval* *If higher increase injection interval*	**2-3 per yr** Testosterone trough level **Annual** FBC LFT Lipids
Nebido	1000 mg every 10-14 weeks	Sample prior to next planned injection – trough level *Option to blood test 3-4 weeks after injection to check peak level.*	Lower 1/3 of local reference range *If lower reduce injection interval and re-test* *If higher increase injection interval and re-test*	**2 per yr** Testosterone trough level **Annual** FBC LFT Lipids

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Appendix 1 – Information about Masculinising Hormone Treatment

Hormone treatment for people assigned female at birth involves the use of testosterone. This can be given by intramuscular injection or by a gel which is applied to the skin each day. This sheet provides information about what changes can be expected as well as the risks of this treatment.

Testosterone treatment will increase the growth of body and facial hair. There is a risk of developing male pattern baldness on your head. There may be redistribution of body fat and an increase in muscles giving a more masculine body shape. Acne can be a problem but should be treated as usual. Mood changes, both positive and negative, may happen but these don't often require treatment. Over time it is likely that your voice will deepen into the male range. There may be a small amount of bone thickening which may help masculinisation.

Taking testosterone causes your clitoris to get bigger which can be uncomfortable at first. You are likely to feel an increase in your sexual drive. Your vagina may also not get lubricated so easily. This may cause pain and discomfort on penetration but you can buy lube for this to help.

Your periods will stop but this can take many months. Some people have a problem with light bleeding which is sometimes called spotting. You are likely to become infertile (not able to have children) and this might still be the case even if you stop taking male hormones. You need to be aware though that you could still become pregnant even when taking masculinising hormones. This means that you should use contraception such as condoms as necessary. You need to think about storing gametes (eggs) if you wish to have biologically-related children in the future. Although hormones are likely to make you infertile, there is still a possibility that if you engage in penile-vaginal intercourse you could become pregnant so you should use contraception if this is a possibility. There are risks if you become pregnant whilst taking testosterone treatment.

Research on the treatment of people assigned female at birth with testosterone is currently limited. More evidence may be found in future about the benefits and risks. Male hormone treatment may cause changes to liver function, haematocrit (a measure of the thickness of the blood), and haemoglobin levels which could require more investigation and could be an

indication of a serious illness. For this reason it is important for you to have your blood tested regularly so that we know if there have been any changes.

There may be long-term risks in taking masculinising hormone treatment. These are not fully known but include higher risks of cancers of the uterus (womb) and ovaries. After 2-3 years of hormone treatment you should think about monitoring for any problems that may occur or having an operation to remove the uterus and ovaries; if you choose to have monitoring you will need to have scans to check the womb and ovaries are healthy - which may include a scan from inside your vagina.

You can stop this treatment at any time. There will be effects such as body hair growth, baldness, a deeper voice and the loss of ability to have children, which may not be reversed if you do.

It is important to have regular blood tests and to attend appointments at our clinic to reduce the chances of unwanted effects. If you are unable to attend appointments regularly we may no longer support your treatment and your GP may decide to stop your treatment.

Declaration

I confirm that I have read and understood the information above.

I confirm that I understand that all testosterone treatment apart from Sustanon is not licenced for the treatment of gender dysphoria. I understand if I receive testosterone in the form of gel or Nebido injection this would be off licence, however I agree to receive this medication.

Signed…….

Patient name…… (DOB…….)

In the presence of:

Signed…….

Clinician name…….

Date…….