| Document title | Author | Version | Approval | Review Date |
|---|---|---|---|---|
| New initiation of Testosterone replacement therapy in men with hypogonadism and testosterone deficiency. | Dr RE Hubbard with input from Dr Z Madlom, Dr D Savage, Dr Muniyappa and Consultant Endocrinologists at DBTH. With reference to Barnsley Shared care and Sheffield guidance document as well as BSSM guidelines and Clinical practice guidelines from the Society of Endocrinology. | FINAL | PMOC 1&2 Date: Dec 2025 | Dec 2027 |

# Shared Care Guideline for Topical (Testogel®, Testavan®) and injectable Testosterone (Nebido®) for adult male patients with hypogonadism.

This guideline does not include Sustanon® 250mg and Prescribing should be retained in secondary care.

Specialist responsibilities

- Assess the patient and provide diagnosis; ensure that this diagnosis is within scope of this shared care protocol (section 2) and communicated to primary care.
- Use a shared decision-making approach; discuss the benefits and risks of the treatment with the patient and/or their carer and provide the appropriate counselling (see section 11) to enable the patient to reach an informed decision. Obtain and document patient consent. Provide an appropriate patient information leaflet.
- Assess for contraindications and cautions (see section 4) and interactions (see section 7).
- Conduct required investigations and initial monitoring (see section 8).
- Initiate and optimise treatment as outlined in section 5.
- Once treatment is optimised, complete the shared care documentation and send to patient's GP practice detailing the diagnosis, current and ongoing dose, any relevant test results and when the next monitoring is required. Include contact information (section 13).
- Prescribe sufficient medication to enable transfer to primary care, including where there are unforeseen delays to transfer of care.
- Conduct the scheduled reviews and monitoring in section 8 and communicate the results to primary care. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in section 9 remains appropriate.
- Provide advice to primary care on the management of adverse effects if required.

Primary care responsibilities

- Respond to the request from the specialist for shared care in writing. It is asked that this be undertaken within 14 days of the request being made, where possible.
- If accepted, prescribe ongoing treatment as detailed in the specialists request and as per section 5, taking into any account potential drug interactions in section 7.
- Adjust the dose of Testosterone prescribed as advised by the specialist.
- It should be noted that Testosterone is a class 4 medication so should only be given for a maximum dose of 30 days' supply.
- Conduct the required monitoring as outlined in section 9. Communicate any abnormal results to the specialist.
- Manage adverse effects as detailed in section 10 and discuss with specialist team when required.
- Stop Testosterone and make an urgent referral to urology if PSA ≥3 and no other causes e.g. UTI, recent instrumentation. To endocrinology specialist if Hct >0.52 to obtain dose reduction advice.
- Stop treatment as advised by the specialist.

Patient and/or carer responsibilities

- Use Testosterone as prescribed and avoid abrupt withdrawal unless advised by the primary care prescriber or specialist.
- Attend regularly for monitoring and review appointments with primary care and specialist and keep contact details up to date with both prescribers. Be aware that medicines may be stopped if they do not attend.
- Report adverse effects to their primary care prescriber. Seek immediate medical attention if they develop any symptoms as detailed in section 11.
- Report the use of any over the counter medications to their primary care prescriber and be aware they should discuss the use of Testosterone with their pharmacist before purchasing any OTC medicines.

## 1. Background

Back to top

This guideline has been developed to support Doncaster and Bassetlaw prescribers to be involved in shared care prescribing for testosterone for the licensed indication of male hypogonadism and/or testosterone insufficiency confirmed by clinical and biochemical features.

*Endocrinology society guidelines advise against routine screening for hypogonadism, and routine prescribing for men over the age of 65 with low testosterone levels without symptoms. Those with symptoms can be offered testosterone therapy after discussion of the risk and benefits.*

**It is important to establish whether the patient has primary or secondary hypogonadism i.e. whether the low testosterone result is due to testicular dysfunction or pituitary dysfunction which can be done by checking LH and FSH.**

**Patients with suspected pituitary dysfunction should be referred URGENTLY to Endocrinology.**

Often patients will present with a cluster of 2-3 symptoms which may include.

- **Low libido**
- **Erectile dysfunction including loss of morning erections**
- **Gynaecomastia**
- **Infertility**
- Non-specific symptoms e.g. fatigue, reduced strength, loss of motivation, irritability, depression, hot flushes, sleep disturbances

Risk factors include:

- **Obesity**
- **Medications, in particular opiates.**
- **Uncontrolled diabetes**
- Patient with history of damage to testes – trauma, orchitis, chemotherapy or radiotherapy, un-descended testis
- Pituitary problems, hypothalamic disorders, Sarcoidosis
- Other medications including anti-epileptic medications, steroids

| Blood Test | Primary hypogonadism | Secondary Hypogonadism |
|---|---|---|
| Testosterone | Low | Low |
| LH and FSH | High | Low/inappropriately normal |
| Prolactin | Normal | Normal/Raised |

Initial diagnosis: To confirm testosterone deficiency in men; Two fasting blood testosterone levels at least 4 weeks apart before 10AM (as testosterone levels show diurnal variation)

Criteria for diagnosis as per BSSM guidelines.

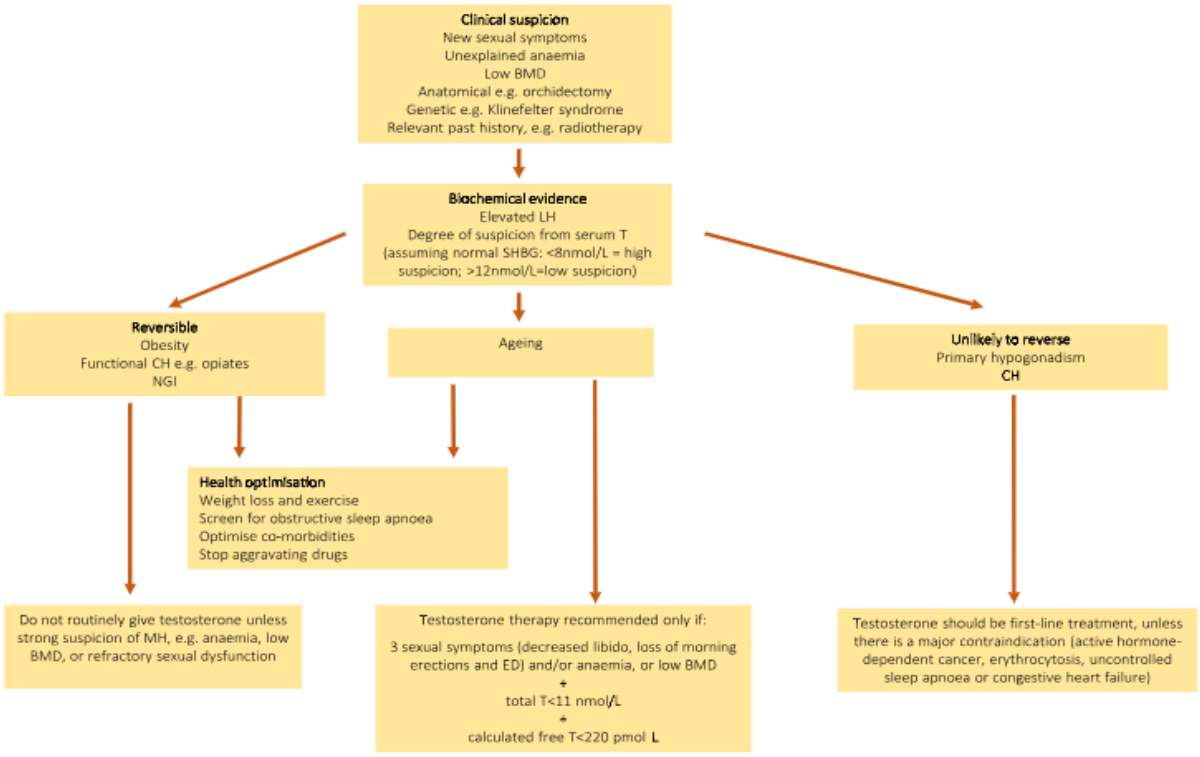


**FIGURE 1** Flowchart for male hypogonadism management. BMD, bone mineral density; CH, central hypogonadism; ED, erectile

- **Confirmed deficiency**: Testosterone level of<8nmol/l is consistent with a diagnosis of hypogonadism
- **Possible deficiency:** 8-12nmol/l could be hypogonadal and can be considered for a trial of Testosterone Replacement Therapy. Hypogonadism is more likely to be present with a testosterone <10.4
- **Not deficient:** If >12nmol/l subject is not hypogonadal and does not require Testosterone replacement

## 2. Indications

Back to top

Hypogonadism due to androgen deficiency in men

## 3. Locally agreed off-label use

Back to top

This shared care does not refer to the off-label use of Testosterone in women – Please refer to the Sheffield shared care guideline which can be found here. https://www.intranet.sheffieldccg.nhs.uk/Downloads/Medicines%20Management/Shared%20Care%20protocols/SCP_testosterone_HRT_women.pdf?UNLID=554530876202211320164 6

This guideline does not refer to prescribing of Testosterone in trans man patients-Please refer to the guideline developed by Porter Brook clinic. https://www.shsc.nhs.uk/sites/default/files/2022-07/Trans%20man%20prescribing%20guidelines.pdf

Complex patients prescribed Sustanon 250 should remain under secondary care.

## 4. Contraindications and cautions

Back to top

This information does not replace the Summary of Product Characteristics (SPC) and should be read in conjunction with it. Please see BNF & SPC for comprehensive information.

**Contraindications:**

- Prostate Cancer- Above age specific limits unless prostate cancer excluded by urologist
- If planning a family in the near future
- Severe untreated obstructive sleep apnoea
- Male breast cancer
- History of liver tumours
- Hypercalcaemia
- Haematocrit >0.54
- Severe lower urinary tract symptoms
- Uncontrolled heart failure
- Thrombophilia
- MI or stroke within the last 6 months.

## 5. Initiation and ongoing dose regime

Back to top

- Transfer of monitoring and prescribing to primary care is normally after the patient's dose has been optimised and with satisfactory investigation results. Due to the significant initial monitoring requirements, transfer to Primary Care would not be expected before 3 months of treatment.
- Testosterone treatment is usually lifelong.
- All dose or formulation adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the primary care clinician.
- Termination of treatment will be the responsibility of the specialist.

**Initial stabilisation:**

It is expected that a person will be under the care of the specialist for approximately 3 months during initial monitoring and stabilisation of dose. It is expected that the initial prescription will be provided by the initiating specialist. *Gels are often used initially as they enable a rapid dose stabilisation and allow assessment of treatment efficacy. It usually takes 2-3 weeks for a steady state testosterone level to be reached in the blood. If patients are not responding to high dose topical therapy, they may be considered for injectable Testosterone treatment.*

**Maintenance dose (following initial stabilisation):**

GP's can be approached to take over prescribing and monitoring once a stable dose has been established, usually at 3 months.

**Conditions requiring dose adjustment:**

Significant weight loss during treatment may require dose adjustment.

## 6. Pharmaceutical aspects -Testavan® 1st Line Treatment

Back to top

| | |
|---|---|
| Route of administration: | **Topical** |
| Formulation: | **Pump 1.15g/23mg per dose. Maximum dose 69mg/day. (3 pumps)** |
| Administration details: | Pumps applied to clean dry healthy skin by the patient himself using the applicator to upper arms and shoulders once daily, ideally in the morning as a thin layer and left to dry for 3-5 minutes. Wash hands after application and cover sites with clothing after gel has dried to avoid transfer. Avoid bathing for at least 2 hours after application. Usual dose 2-3 pumps. |
| Other important information: | Therapy should be discontinued if the blood testosterone levels consistently exceed the normal range at the lowest daily dose of 23 mg or if blood testosterone levels in the normal range cannot be achieved with the highest dose of 69 mg. |

| | |
|---|---|
| **6. Pharmaceutical aspects – Testogel pump®** Back to top | |
| Route of administration: | **Topical** |
| Formulation: | **16.2mg/1.25g per pump which delivers 20.25g Testosterone.**<br>**Maximum dose 81mg/day (4 pumps)** |
| Administration details: | Apply a thin layer of gel on clean, dry healthy skin over upper arms and shoulders. Allow to dry for 3-5 minutes before dressing. Wash hands with soap after application and avoid bathing for at least 2 hours. |
| Other important information: | BNF licensed maximum dose 81mg/day. |
| **6. Pharmaceutical aspects – Testosterone decanoate (Nebido®)** Back to top | |
| Route of administration: | **Deep IM** |
| Formulation: | **1000mg/4ml** |
| Administration details: | Slow intramuscular injection into the gluteal muscle by a qualified health care professional with the patient laid down over 1-2 minutes to reduce the risk of lipid embolism. Usually given every 10-14 weeks. |
| Other important information: | **May be given every 8-14 weeks depending on Testosterone levels, usually at 10 weeks. Specialist to advise on dose frequency.** |

## 7. Significant medicine interactions

Back to top

The following list is not exhaustive. Please see BNF or SPC for comprehensive information and recommended management.

- Warfarin – May need increased INR monitoring
- Co-administration with corticosteroids can increase the risk of oedema
- Anti-diabetic medication doses may require adjustment

## 8. Baseline investigations, initial monitoring and ongoing monitoring to be undertaken by specialist

Back to top

Monitoring at baseline and during initiation is the responsibility of the specialist; only once the patient is optimised on the chosen medication with no anticipated further changes expected in immediate future will prescribing and monitoring be transferred to primary care.

**Baseline investigations by GP before referral:**

- Assessment of symptoms consistent with testosterone deficiency
- PR examination, BMI, BP, assessment of cardiovascular risk factors
- FBC, UE, LFT, SHBG, bone profile, fasting lipids, LH, FSH, Prolactin, PSA
    - FSH and LH help distinguish between primary and secondary causes of hypogonadism.
    - SHBG is helpful as testosterone alone is not always reliable
- Two testosterone results <8 at least 1 week apart done ideally at 9AM but definitely before 10AM
- Seek advice for patients where testosterone level is 8-12.

**Baseline investigations by specialist:**

- FBC, UE, LFT, bone profile, fasting lipids, LH, FSH, Prolactin, Testosterone, PSA if not done in primary care
- Consideration of baseline DEXA scanning (if history of osteoporosis or risk factors)

**Initial monitoring by specialist:**

- 2 weeks -FBC and Testosterone levels 2-4 hours post application of gel
- 6-8 weeks- Clinical assessment of symptoms, dose increase if required and Testosterone levels
- 3 months – Clinical assessment of symptoms, testosterone levels. If stable, consider shared care with GP by completing proforma.

Also: Testosterone levels 2-3 weeks after any dose changes are the responsibility of the specialist.

Note: For gel preparations blood levels should be taken 2-4 hours post dose. For injectable preparations up to 48 hours pre-next injection (trough levels)

**Ongoing monitoring:**

- Yearly: FBC, LFT, PSA, BMI, testosterone levels and Blood pressure.
- PR examination is no longer routinely recommended in the BSSM guidelines unless there are new urinary symptoms, or PSA rises by >1.4 in 12 months.
- There is no convincing evidence that testosterone replacement therapy causes prostate cancer, but it can aggravate the symptoms of advanced or metastatic prostate cancer
- Testosterone levels – 2-4 hours post application for gel. Maximum 48 hours BEFORE next injection for IM injection. Levels outside of this cannot be interpreted
- Advise primary care if ongoing DEXA monitoring is advised.

When a patient is reviewed, advise primary care AND the patient whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in section 9 remains appropriate. Testosterone replacement should be considered long term if the patient finds it beneficial, well tolerated and annual monitoring is up to date.

## 9. Ongoing monitoring requirements to be undertaken by primary care

Back to top

See section 10 for further guidance on management of adverse effects/responding to monitoring results.

| Monitoring | Frequency |
|---|---|
| **Medication review to ensure compliance with treatment and side effects.** | **Yearly** |
| **Assessment of any new urinary symptoms +/- PR examination if symptoms indicate, BMI and BP addressing cardiovascular risk factors** | **Yearly** |
| **FBC, UE, PSA, LFT, testosterone levels** | **At 6 months, then 12 months, yearly thereafter.** |

## 10. Adverse effects and other management

Back to top

**Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit** www.mhra.gov.uk/yellowcard

For information on incidence of ADRs see relevant summaries of product characteristics

Common side effects include local application site reactions, acne, facial hair growth, weight gain, facial flushing, headache, hypertension, increase in PSA, increase in RBC, Hb and haematocrit. Androgens may accelerate the progression of sub-clinical prostatic cancer and benign prostatic hyperplasia. Gynaecomastia has also been reported. Sleep apnoea may be worsened; symptoms of excessive daytime sleepiness and witnessed apnoea should be inquired.

| Result | Suggested response |
|---|---|
| As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance<br>*The table below has been reproduced from the Barnsley guidance with consent from the author.* | |
| **Testosterone levels** | Aim for 15. (Range 12-17) If levels remain less than 8.4 nmol/L pre-injection dose, then injection interval may need to be shortened. If levels are greater than 28.7nmol/l pre-injection dose, then injection interval may need to be lengthened. |
| **FBC, haematocrit** | If greater than 18 g/dL discuss venesection with clinician responsible for care. Check FBC in 28 days. Consider dose reduction or change to preparation. |
| **LFT's** | If ALT is elevated to greater than 100 IU/L, repeat in 7 – 10 days. If continues to rise discuss with clinician responsible for care. |
| **PSA** | If PSA is greater than 3 ug/L exclude UTI and question patient regarding prostatic symptoms. Consider stopping treatment and suspected cancer referral to urology if PSA remains elevated. |
| **Cholesterol, HDL, Triglycerides** | Abnormal lipid profile (cholesterol greater than 5.5 nmol/L with HDL less than 1.0 nmol/L or triglycerides greater than 1.9 nmol/L) prior to or during Nebido® treatment should be investigated and treated in the context of overall health by the clinician responsible. Any significant worsening of the lipid profile on Nebido® should result in stopping treatment prior to further investigation. |
| **Poor response to treatment** | Effects on libido may appear after 3 weeks of treatment, and plateau at 6 weeks. Changes in erectile function and ejaculation may require up to 6 months. Effects on quality of life, and depressive mood, may become detectable within 1 month, may take longer and sometimes up to 12 months. Discuss treatment discontinuation with specialist if poor response persists. |
| **Substantial worsening of LUTS or prostate abnormality on PR examination** | Refer to urologist, following suspected cancer guidelines as needed. |
| **Acne** | Treat as required |
| **Gynaecomastia** | A+G to endocrinologist |
| **Exacerbation of cardiovascular symptoms e.g. oedema** | Stop treatment and A+G to endocrinologist |

## 11. Advice to patients and carers

Back to top

The specialist will counsel the patient about the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual medicines.

**The patient should be advised:**

- If they experience acute leg swelling, shortness of breath or acute limb weakness they should attend the local emergency department.
- If they develop symptoms of urinary urgency, frequency, dysuria, difficulty initiating stream or terminal dribbling an MSU should be arranged, and the patient reviewed by the GP.

## 12. Pregnancy, paternal exposure and breast feeding

Back to top

It is the responsibility of the specialist to provide advice on the need for contraception to male and patients on initiation and at each review, but the ongoing responsibility for providing this advice rests with both the primary care prescriber and the specialist.

Testosterone can be topically transferred to others.

**Paternal exposure**: Testosterone prescribing is not suitable for those experiencing infertility.

## 13. Specialist contact information

Back to top

Name: Dr S Muniyappa, Dr R Teklebeehan, Dr A Oprescu

Role and specialty: Consultant Endocrinologist's

Email address: advice-dbth.diabsec@nhs.net

## 14. Additional information

Back to top

Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed. Ensure that the specialist is informed in writing of any changes to the patient's GP or their contact details.

## 15. References

Back to top


- https://www.sheffieldccgportal.co.uk/pathways/primary-care-management-pathway-low-testosterone-in-adult-men
- https://best.barnsleyccg.nhs.uk/clinical-support/medicines/shared-care-guidelines/Testosterone%20Shared%20Care%20Guidlines.pdf?UNLID=579747845202210162026 6
- https://bssm.org.uk/wp-content/uploads/2023/08/Trends-Urol-Men-s-Health-2023-Hackett-A-practical-guide-to-the-assessment-and-management-of-testosterone-deficiency-1.pdf


## 16. Other relevant national guidance

- Shared Care for Medicines Guidance – A Standard Approach (RMOC). Available from https://www.sps.nhs.uk/articles/rmoc-shared-care-guidance/
- NHSE policy – Responsibility for prescribing between primary & secondary/tertiary care. Available from https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/
- General Medical Council. Good practice in prescribing and managing medicines and devices. Shared care. Available from https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/shared-care
- NICE NG197: Shared decision making. Last updated June 2021. https://www.nice.org.uk/guidance/ng197/.

## 17. Local arrangements for referral

Back to top

Define the referral procedure from hospital to primary care prescriber & route of return should the patient's condition change.

Once patient has been stabilised at 3 months of monitoring and dose, consideration for referral back to primary care should be considered.

The treatment plan should include the expected length of treatment and the dose frequency if using injectable testosterone therapy which will often be lifelong.

Queries should be submitted via Endocrinology Advice and Guidance.



Updated November 2025 V1.
Approved by Doncaster and Bassetlaw PMOC Section 1&2 December 2025
This document will be reviewed in light of new or emerging evidence or by December 2027.