BNSSG Shared Care Guidance
Please complete all sections

Section 1: Heading

Drug	Testosterone intramuscular injection
Amber *three months*	
Indication	Testosterone replacement therapy for male hypogonadism

Section 2: Treatment Schedule

Usual dose and frequency of administration *(Please indicate if this is licensed or unlicensed and any relevant dosing information)*	Intramuscular injection: - Sustanon - 250 mg every 3-5 weeks - Nebido - 1000mg (1 x 4ml ampoule) every 10-14 weeks See individual product SPC and BNF for administration instructions.
Route and formulation	Deep intramuscular injection: - Sustanon 250mg/1 ml solution for injection vials (testosterone decanoate, isocaproate, phenylpropionate and propionate) - Nebido – 1 gram/ 4 ml solution for injection vials (testosterone undecanoate) The goal is for patients to self-administer. Practices may have to administer the initial injections and teach patients or a partner how to self-administer.
Duration of treatment	Hypogonadism is usually longstanding; therefore the treatment duration is usually indefinite, often lifelong till age 75, or longer if appropriate. Duration determined by secondary care endocrinology team.

Section 3: Monitoring

Please give details of any tests that are required before or during treatment, including frequency, responsibilities (please state whether they will be undertaken in primary or secondary care), cause for adjustment and when it is required to refer back to the specialist.

Baseline tests – where appropriate
Baseline tests by secondary care endocrinology team: Blood pressure; Check for ankle oedema; Blood tests: full blood count, liver function tests, lipids, morning testosterone, sex hormone binding globulin; In addition, in men over 40 years old blood test for PSA.
Subsequent tests – where appropriate *(Please indicate who takes responsibility for taking bloods and interpreting results)*

Patients to be reviewed in secondary care at 3-6 months. Future appointments to be decided by specialist based on response to treatment. Monitoring required as follows:

Test	Frequency	Who by	Action/management
Testosterone trough levels (blood sample taken immediately before the next dose)	Intramuscular injection: - Before 4th injection (usually at 3-6 months after starting): o Sustanon: at around 2-4 months o Nebido: at around 6-10 months - At 12 months - Then annually	Primary Care	Testosterone normal range 8.7-29nmol/L. Aim to achieve trough levels in low-mid normal range. If pre-injection levels remain <8.7nmol/L then interval may need to be shortened.
Full blood count and liver function tests	At 3-6 months after starting treatment, 12 months, then annually	Primary Care	If haemoglobin >185 g/L and/or haematocrit (Hct) >0.52 L/L then discuss with specialist. The testosterone injection interval may need to be lengthened. If liver function tests are abnormal (results are 1.5 times the upper limit of the reference range), then consider ultrasound, full liver screen and referral to liver clinic.
Lipids	Three months after starting treatment	Primary Care	Repeat if abnormal. Lipid management to be determined by lipid risk calculator.
PSA (men >40 years old)	At 3-6 months after starting treatment, 12 months, then annually	Primary Care	If PSA rises above age appropriate levels then to refer to urologist and withhold medicine until review has occurred.
Clinical monitoring - ask about urinary symptoms	Annually	Primary Care	If substantial changes to lower urinary tract symptoms, further investigation required including PSA. If abnormal, withhold treatment and seek specialist advice.

Section 4: Side Effects

Please list only the most pertinent side effects and management. Please provide guidance on when the GP should refer back to the specialist. For everything else, please see BNF or SPC.

Side effects and management

Side effect	Frequency/severity	Action/management
Acne and injection site discomfort	Very common	
Hypertension	Common	Treat hypertension as per local guidelines
Polycythaemia	Common	Stop treatment or reduce dose – see advice from specialist endocrinology team.
Re-expansion of prostate aggravating pre-existing or causing new	Common	If any concerns about possible adverse effects, withhold any further injections and seek

prostatic symptoms		advice from specialist endocrinology team
Androgenic effects (see SPC)	Common	
Does not cause or increase risk of prostate cancer but may increase growth rate of pre-existing undetected prostate cancer.	Common	
New sleep apnoea	Frequency not known	

Referral back to specialist	Suspected adverse effect; Raised haemoglobin and/ or haematocrit; Rising/ raised PSA; Loss of efficacy

Section 5: Other Issues

(e.g. Drug Interactions, Contra-indications, Cautions, Special Recommendations)

Please list only the most pertinent action for GP to take (For full list please see BNF or SPC)

Issues	1. Contraindications: Breast cancer in males; history of liver tumours; unexplained, untreated hypercalcaemia; prostate cancer, untreated sleep apnoea, severe prostatic symptoms. Sustanon contains arachis (peanut) oil therefore it is contraindicated in patients allergic to peanuts or soya 2. Cautions: In patients suffering from severe cardiac, hepatic or renal insufficiency or ischaemic heart disease, treatment with testosterone may cause severe complications characterised by oedema with or without congestive cardiac failure. In such cases treatment must be stopped immediately. Erythrocytosis; prostatic hypertrophy; diabetes mellitus; elderly; epilepsy; hypertension; ischaemic heart disease; migraine; pre-pubertal boys (fusion of epiphyses is hastened and may result in short stature) - statural growth and sexual development should be monitored; skeletal metastases - risk of hypercalcaemia or hypercalciuria (if this occurs, treat appropriately and restart treatment once normal serum calcium concentration restored); sleep apnoea; stop treatment or reduce dose if severe polycythaemia occurs; risk factors for venous thromboembolism; thrombophilia—increased risk of thrombosis tumours - risk of hypercalcaemia or hypercalciuria (if this occurs, treat appropriately and restart treatment once normal serum calcium concentration restored). 3. Special recommendations: In most men, and always in those over 40 years, sustanon should only be started after a 3 month trial of transdermal testosterone replacement has confirmed no significant adverse effects. Sustanon should not usually be used in children under 18 years old, young men who have not stopped growing, delayed puberty or for puberty induction. Because dose titration is difficult it may result in premature epiphyseal fusion and short stature. 4. Drug interactions: Anticoagulants: testosterone may enhance the anticoagulant effect of coumarins and phenindione. Antidiabetics: the hypoglycaemic effect of some antidiabetics may be enhanced.

Reminder to ask patient about specific problems	Ask about any suspected adverse effects, ankle swelling, urinary symptoms, injection site discomfort, gynaecomastia, personality changes.

Section 6: Advice to the patient

Advice for prescribing clinician to inform patient

1. Advise about purpose of treatment and potential adverse effects as above. Advise to contact the supervising physician if any suspected adverse effects.
2. Specialist to advise that testosterone replacement may reduce testosterone production which may lead to a reduction in sperm production and affect fertility. Advise to discuss with specialist before starting treatment if considering having children in the future.

Section 7: Generic principles of shared care for SECONDARY CARE

Please do not amend.

Core responsibilities

1. Initiating treatment and prescribing for the length of time specified in **section 1.**
2. Undertaking the clinical assessment and monitoring for the length of time specified in **section 1** and thereafter undertaking any ongoing monitoring as detailed in **section 3.**
3. Communicate details of the above in 1 and 2 to GP within the first month of treatment. This information should be transferred in a timely manner.
4. Refer patients to GP and provide information of further action where appropriate e.g. if blood test is due.
5. To provide advice to primary care when appropriate.
6. Review concurrent medications for potential interaction prior to initiation of drug specified in **section 1.**
7. Stopping treatment where appropriate or providing advice on when to stop.
8. Reporting adverse events to the MHRA.
9. Reminder to ask patients about particular problems see **section 5.**

Section 8: Generic principles of shared care for PRIMARY CARE

Please do not amend.

Core responsibilities

1. Responsible for taking over prescribing after the length of time specified in **section 1.**
2. Responsible for any clinical assessment and monitoring if detailed in **section 3** after the length of time specified in **section 1.**
3. Review of any new concurrent medications for potential interactions.
4. Reporting adverse events to the MHRA.
5. Refer for advice to specialist where appropriate.
6. Reminder to ask patients about particular problems see **section 5.**

Section 10: Contact Details

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Section 11: Document Details

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Section 12: Collaboration

All shared care protocols should be BNSSG wide where possible. Specialists in any one discipline are encouraged to collaborate across the health community in preparing shared care guidance. Please give details

1. NBT Endocrinology Team
2. UHBW Endocrinology Team

Section 13: References

Please list references

1. British National Formulary
2. Guidelines on the management of sexual problems in men: the role of androgens. Society for endocrinology, Royal college of physicians, Royal college of pathologists, British society for sexual medicine, British association of urological surgeons, British fertility society, British menopause society, British association for sexual health and HIV. Wylie K et al, 2010.
3. Shalender Bhasin, Juan P. Brito, Glenn R. Cunningham, et al. Testosterone Therapy in Men With Hypogonadism: An Endocrine Society* Clinical Practice Guideline. J Clin Endocrinol Metab, May 2018, 103(5):1715–1744
4. Geoff Hackett, Michael Kirby, David Edwards, Thomas Hugh Jones at al. British Society for Sexual Medicine Guidelines on Adult Testosterone Deficiency, With Statements for UK Practice. J Sex Med 2017;14:1504e1523.
5. https://www.nebido.com/en/hcp/product-information/faq-nebido/