Testosterone therapy *for Hypogonadism and Constitutional Delay in Growth and Puberty in children and adolescents* – Shared Care Protocol Agreement		
V2.0	Last reviewed: January 2023	Review date: January 2026

NHS
Nottinghamshire Area Prescribing Committee

NOTTINGHAMSHIRE AREA PRESCRIBING COMMITTEE SHARED CARE PROTOCOL AGREEMENT

(*Sustanon®-250injection and Tostran® medicine(s) for Hypogonadism and Constitutional Delay in Growth and Puberty in children and adolescents*)

This shared care protocol is for children and young people assigned male sex at birth who have delayed puberty and/or hypogonadotropic hypogonadism. It does NOT apply to children and young people with gender identity difficulties

OBJECTIVES

- To outline the referral criteria for shared-care, define responsibilities of the Paediatric Endocrinology team and GP.
- To provide an information summary on the prescribing and monitoring of testosterone in children and adolescents for
    - hypogonadism and
    - constitutional delay in growth and puberty (CDGP)

REFERRAL CRITERIA

- Prescribing responsibility will only be transferred when it is agreed by the specialist and the patient's primary care prescriber.

PROCESS FOR TRANSFERRING PRESCRIBING TO PRIMARY CARE

- The request for shared care should include individual patient information, outlining all relevant aspects of the patients care and which includes direction to the specific information sheets at www.nottsapc.nhs.uk.

- If the GP does not agree to share care for the patient then he/she will inform the Specialist of his/her decision in writing within 14 days, outlining the reason for decline. Agreement can be assumed if the GP does not provide written decline.

- In cases where shared care arrangements are not in place, or where problems have arisen within the agreement and patient care may be affected, the responsibility for the patient's management including prescribing reverts back to the specialist.

CONDITION TO BE TREATED

The aim of testosterone replacement therapy is to mimic the normal cadence of puberty and match requirements at different stages of pubertal development in patients with Hypogonadism and CDGP. Testosterone replacement therapy is used to induce development of secondary sexual characteristics and promote linear growth, normal accrual of muscle mass and bone density while avoiding premature epiphyseal plate closure. Testosterone replacement therapy is usually started from the age of 12-14 years and the dose is reviewed 6 monthly increasing progressively over 24-36 months until the adult maintenance dose is

reached. The maintenance dose of testosterone replacement is continued into adult life. In the case of CDGP the testosterone is stopped when there is established endogenous puberty, as assessed by the specialist.

All boys with delayed puberty (absence of signs of secondary sexual development i.e. testicular volume less than 4 mL at 14 years of age) should be referred to paediatric endocrinology for assessment. CDGP is the most common cause but it can be extremely difficult in the early stages of puberty to differentiate CDGP from Hypogonadism. Boys with CDGP/Hypogonadism may manifest with psychological distress because of their lack of growth and pubertal progression, which can affect their school performance, social relationships and can affect their psychological wellbeing. A course of testosterone treatment should be offered in order to enhance growth rate and expedite the features of puberty. In those with CDGP who receive testosterone treatment, the intervention is well tolerated, highly effective and regarded as a standard therapeutic option.

Monitoring of growth and pubertal status is paramount in boys who receive testosterone replacement treatment. This is done by the paediatric endocrine specialist team every 6 months.

NATIONAL/ LOCAL GUIDANCE

The British Society for Paediatric Endocrinology and Diabetes (BSPED) recommend several licensed preparations of testosterone for use off-label in children, including injectable, oral capsule and testosterone cream/gel. Oral capsule preparations have been discontinued. Other licenced testosterone preparations that are available (transdermal gel, patch and implant) are not recommended by BSPED for use in children.

CLINCAL INFORMATION

See information sheet Testosterone (Sustanon® injection and Tostran® gel) in male children and adolescents.

AREAS OF RESPONSIBILITY

(include any other medicine specific responsibilities)

Specialist's Roles and Responsibilities

1. The specialist will confirm the working diagnosis.
2. The specialist will recommend testosterone therapy and specify the type and dose.
3. If shared care is considered appropriate for the patient and the patient's treatment regimen is confirmed, the specialist will contact the GP as soon as it is recommended. This is to provide notice, time to agree and organisation of prescriptions
4. The specialist will provide the patient's GP with the following information:
   - diagnosis of the patient's condition with the relevant clinical details.
   - details of the patient's treatment to date
   - details of treatments to be undertaken by GP*
   - details of other treatments being received by the patient that are not included in shared care
   - details of monitoring arrangements

- details of any relevant drug interactions

*Including reasons for choice of treatment, medicine or medicine combination, frequency of treatment, number of months of treatment to be given before review by the consultant.

5. Whenever the specialist sees the patient, he/she will
   - send a written summary within 14 days to the patient's GP.
   - communicate any dosage changes made to the patient and GP
6. The specialist team will be able to provide training for primary care prescribers if necessary to support the shared care agreement.
7. Contact details for during working and non-working hours will be made available
8. The specialist will provide the patient with details of their treatment; follow up appointments, monitoring requirements and nurse specialist contact details.
9. The specialist will review the patient's pubertal development, growth and response to treatment at 4 to 6 monthly intervals. Monitoring will include height and weight measurements, pubertal staging, bone age assessment at approximately 12 monthly intervals if appropriate and hormonal measurements as indicated.
10. The specialist will highlight the importance of monitoring to the patient and explain the potential withdrawal of treatment if monitoring appointments are not attended

Primary Care Prescriber's Roles and Responsibilities

If the primary care prescriber does not agree to shared care for the patient then he/ she will inform the Specialist of his/her decision in writing within 14 days.

The Primary Care Prescriber will be responsible for:

1. Ensuring that he/she has the information and knowledge to understand the therapeutic issues relating to the patients clinical condition.
2. Undergoing any additional training necessary in order to carry out the prescribing and monitoring necessary
3. Agreeing that in his / her opinion the patient should receive shared care for the diagnosed condition unless good reasons exist for the prescription and administration to remain within secondary care.
4. Prescribing the testosterone therapy in accordance with the written instructions contained within the information sheets and communicating any changes of dosage made in primary care to the patient. It is the responsibility of the prescriber that makes a dose change to communicate this to the patient.
5. Where applicable keep the patient-held monitoring booklet up to date with the results of investigations changes in dose and alterations in management and take any actions necessary. It is the responsibility of the clinician to action the results from monitoring, in accordance with this shared care guideline, and thereby prescribing for the patient to complete the patients record with the necessary information.
6. Reporting any adverse effect in the treatment of the patient to the specialist team.
7. The Primary Care Prescriber will ensure that the patient is monitored as outlined in the information sheet(s) and will take the advice of the referring specialist if there are any amendments to the suggested monitoring schedule.
8. The Primary Care Prescriber will ensure that the patient is given the appropriate appointments for follow up and monitoring, and that defaulters from follow up are contacted to arrange alternative appointments. It is the Primary Care Prescribers responsibility to decide whether to continue treatment in a patient who does not attend appointments required for follow up and monitoring

Community Pharmacist Roles and Responsibilities

1. Professionally check prescriptions to ensure they are safe for the patient and contact the GP if necessary to clarify their intentions.
2. Fulfil legal prescriptions for medication for the patient unless they are considered unsafe.
3. Counsel the patient on the proper use of their medication.
4. Advise patients suspected of experiencing an adverse reaction to their medicines to contact their GP/specialist team.

Patient's Roles and Responsibilities

1. Take their medication as agreed, unless otherwise instructed by an appropriate healthcare professional.
2. Attend all follow-up appointments with GP and specialist. If they are unable to attend any appointments they should inform the relevant practitioner as soon as possible and arrange an alternative appointment.
3. Inform all healthcare professionals of their current medication prior to receiving any new prescribed or over-the-counter medication.
4. Report all suspected adverse reactions to medicines to their GP/specialist team.
5. Store their medication securely away from children.
6. Read the information supplied by their GP, specialist and pharmacist and contact the relevant practitioner if they do not understand any of the information given

REFERENCES

The British Society for Paediatrics Endocrinology and Diabetes (BSPED) guideline: Testosterone Therapy in Infancy and Adolescence. Jan-18. Available at https://www.bsped.org.uk/media/1640/testosterone-replacement-guidelines-final-approved-2942019.pdf (accessed December 2022)

Acknowledgements

Elements of this shared care protocol are adapted from Leicestershire Medicines Strategy Group shared care protocol for children and adolescents for induction of and progression through puberty in hypogonadotrophic hypogonadism (HH), hypogonadism due to primary testicular failure (PTF) and in constitutional delay of growth and puberty (CDGP).

.

Specialist CONTACT DETAILS (In Hours)

Consultant Paediatric Endocrinologists
Secretary Telephone Number: 0115 924 9924 Ext 82336

Paediatric Endocrine specialist Nurse
Telephone Number: 0115 924 9924 Ext 85123

Paediatric Pharmacy Team
Telephone Number: 0115 924 9924 Ext 84410

Specialist CONTACT DETAILS (Out of Hours)

For Medical Professionals - Ring 0115 924 9924 and ask to speak to the Paediatric Endocrinology Consultant on call.

For Patients – Ring 0115 924 9924 and ask to bleep the paediatric medical registrar on call.

Version Control- **Testosterone Therapy for Hypogonadism and Constitutional Delay in Growth and Puberty in children and adolescents**			
Version	Author(s)	Date	Changes
2.0	Vimbayi Mushayi, Specialist Interface Medicine Optimisation Pharmacist, Nottingham and Nottinghamshire ICB In consultation with Dr Tabitha Randell Consultant Paediatric Endocrinologists, Nottingham University Hospitals (NUH),	January 2023	• Added standard header and version control • Removed footer • Added information about the guidance not being applicable to children and adolescences with gender identity difficulties • Added information about oral preparation being discontinued.
1.0	Deepa Tailor, Senior Medicine Optimisation Pharmacist, NHS Nottingham and Nottinghamshire CCGs In consultation with Dr Tabitha Randell, Dr Louise Denvir and Dr Pooja Sachdev Consultant Paediatric Endocrinologists, Nottingham University Hospitals (NUH), Andrew Wignell- Paediatric Pharmacist NUH	January 2020	