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Royal Cornwall Hospitals NHS Trust

Growth Hormone (Somatropin and Somatrogon) for Paediatric Use Shared Care Guideline

V3.1

May 2023

1. Aim/Purpose of this Guideline

1.1. This guideline applies to medical, nursing and pharmacy staff in the safe and appropriate prescription and administration of growth hormone (Somatropin and Somatrogon) when used in children up to 16 years of age.

1.2. This shared care guideline sets out details for the sharing of care of children with growth hormone deficiency prescribed Somatropin or Somatrogon. The somatropin section of this guideline is very strongly based on that suggested by the British Society for Paediatric Endocrinology and Diabetes and its use is acknowledged. This guideline provides additional limited information necessary to aid in the treatment of these patients. As with all shared care guidelines they highlight relevant prescribing issues but should be used in conjunction with relevant NICE guidance, the BNF, ABPI summary of product characteristics and do not replace them.

1.3. This version supersedes any previous versions of this document.

Data Protection Act 2018 (General Data Protection Regulation – GDPR) Legislation

The Trust has a duty under the Data Protection Act 2018 and General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team

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2. The Guidance

2.1. Growth hormone is produced by the anterior pituitary gland. It has a role in the regulation of protein, lipid and carbohydrate metabolism, as well as in increasing growth in children.

2.2. Extensive surveys have not suggested an increased risk of tumours or leukaemia with r-hGH therapy compared with similar patients who have not received therapy when replacement doses are physiological in confirmed growth hormone insufficiency/deficiency (GHD).

2.2.1. Recombinant human growth hormone (somatropin) treatment is recommended for the treatment of children with GH deficiency in the following circumstances:

1. Growth disturbance in children with GHD causing short stature.

2. Growth disturbance in girls with Turner Syndrome confirmed by chromosomal analysis.

3. Growth disturbance in children with chronic renal failure.

4. Improvement in growth and body composition in children with Prader-Willi Syndrome confirmed by chromosomal analysis.

5. Growth disturbance in children born Small for Gestational age.

6. Growth disturbance associated with SHOX deficiency confirmed by DNA analysis.

2.2.2. Somatrogon is indicated for the treatment of children and adolescents from 3 years of age with growth disturbance due to insufficient secretion of growth hormone.

2.2.3. Diagnosis is based on a combination of growth measurement, skeletal examination and imaging and biochemical measurement. Exclusion of other possible causes of growth failure will be appropriate.

2.2.4. When an insulin stress test is contraindicated (e.g. epilepsy, ischaemic heart disease) the use of a glucagon (or arginine) test alone will be appropriate.

2.3. **Preparations and Dosage**

2.3.1. Somatropin is human growth hormone produced by recombinant DNA technology. Its amino acid sequence is identical to that of natural human GH. Somatragon works in a similar way, but it is a weekly injection instead of a daily one. Once-weekly dosing with somatrogon is achieved with C-terminal peptide technology, which extends the half-life of human growth hormone.

2.3.2. The Specialist Team will advise on the preparation to be used. The Specialist Team will advise on the preparation to be used. In general, the daily product used is Omnitrope Surepal, a biosimilar growth hormone based on cost-effectiveness as advised by CIOS ICB and following discussion with patient and/or parents, although any of the other preparations may be started and continued. The weekly somatrogon (Ngenla) has the advantage of less frequent injections.

2.3.3. Somatropin treatment is administered by a daily subcutaneous injection with the dose dependent upon the indication, whereas somatrogon is a weekly injection. The specialist (Consultant Paediatric Endocrinologist or Consultant Paediatrician with expertise in growth disorders) will suggest the starting dose regime and the way it is to be increased initially. Adjustments will be required intermittently. Prescribing should always be in keeping with guidelines for r-hGH published by NICE.

2.3.4. For somatrogon, If a dose is missed, somatrogon should be administered as soon as possible within 3 days after the missed dose, and then the usual once-weekly dosing schedule should be resumed.

2.4. Contraindications and Precautions

2.4.1. Contraindications are:

- Hypersensitivity to the product or any excipient of the formulation chosen.
- Evidence of tumour activity (complete any anti-tumour therapy and ensure that intracranial lesions are inactive before starting).
- After renal transplantation or for growth promotion in children with closed epiphyses (or near closure in Prader-Willi Syndrome).
- Patients in critical care are not recommended growth hormone.
- Severe obesity or severe respiratory syndrome in Prader-Willi Syndrome.

2.4.2. Precautions are:

- Diabetes mellitus (adjustment of antidiabetic therapy may be necessary).
- Papilloedema.
- Deficiencies of other pituitary hormones.
- ACTH deficiency – treatment with steroid replacement should precede other hormone replacement.
- Hypothyrodism – manufacturers recommend periodic thyroid function tests but are of limited evidence of clinical value.
- History of malignant disease.
- Resolved intracranial hypertension (monitor closely).
- Rotate subcutaneous injection sites to prevent lipoatrophy.

2.5. Monitoring

2.5.1. Specialist Team

- The consultant is responsible for initial and ongoing assessment of the patient.
- Adrenal deficiency should be assessed in the initial investigation and replacement therapy should be initiated before somatropin is considered.
- Somatropin or somatrogon dose should be adjusted according to clinical response. The lowest effective dose should be used. Patients should initially receive treatment on the basis of a dose titration and stabilisation for 3 months followed by a 9 months trial of therapy at a maintenance dose.

- The consultant will carry out regular checks on haemoglobin A1c, blood glucose, insulin-like growth hormone (IGH-1) and annually thyroid function tests.

- Insulin treated diabetic patients may require adjustment of their insulin dose on initiation of therapy. If necessary insulin dosage alteration will be the responsibility of the consultant based on the above monitoring.

2.5.2. General Practice

- There are no specific biochemical monitoring requirements for the GP to undertake.

- A non-urgent referral should be made to the consultant if hypothyroidism is suspected or identified.

2.6. Side Effects

Side effects include:

- Skin reactions at the injection site and loss or increase of adipose tissue at injection site.
- Idiopathic intracranial hypertension associated with severe headache and papilloedema.
- Hypothyroidism.
- Hypertension.
- Insulin insensitivity.
- Insomnia.
- Myalgia.
- Paraesthesia.
- Antibody formation but rarely of physiological relevance.
- Fluid retention and peripheral oedema but not commonly in children.

2.7. Significant Drug Interactions

2.7.1. Corticosteroids:

Growth promoting effect may be inhibited. Interactions do not generally apply to corticosteroids used for topical action (including inhalers).

2.7.2. Oestrogens:

Higher doses of somatropin or somatrogon may be needed with oral oestrogen replacement therapy. Interaction with combined oral contraceptives may also apply to combined contraceptive patches. In the case of HRT, low doses are unlikely to induce interactions.

2.7.3. **Anticonvulsants and Ciclosporin:**

Clearance of these compounds may be increased by somatropin or somatrogon resulting in lower plasma levels of these compounds.

2.8. **Areas of Responsibility for the Sharing of Care**

2.8.1. These are suggested ways in which the responsibilities for the management of paediatric patients with growth hormone deficiency who are prescribed somatropin or somatrogon can be shared between the specialist and the general practitioners. The expectation is that these guidelines should provide sufficient information to enable GPs to be confident to take clinical and legal responsibility for prescribing these drugs. If a specialist asks the GP to prescribe this drug the GP should reply to this request as soon as practical. Sharing of care assumes communication between the specialist, GP and patient. The intention to share care should be explained to the patient and be accepted by them.

2.8.2. **In the NHS E guidelines on responsibility for prescribing (January 2018) between hospitals and GPs, it is advised that legal responsibility for prescribing lies with the doctor who signs the prescription.**

2.8.3. **Specialist:**

- Selection of appropriate preparation.
- Initiation of drug treatment and stabilisation of patient's condition over 3 months for dose stabilisation.
- After the stabilisation period ask the GP whether they are willing to participate in shared care using the suggested wording template (Appendix 3).
- A decision on continuing therapy will be taken by the consultant after a further 6 months of prescribing in primary care.
- Provide the patient or patient's carer with suitable written and verbal information about the drug prior to starting medication and discuss the benefits and side effects of treatment.
- Ensure that training on reconstitution, administration and storage of GH is provided for the patient or carer.
- Prescribing the drug until the patient's condition/dose is stabilised and the GP agrees to take over responsibility for prescribing (usually 3 months).
- Specify review dates at clinically relevant time intervals. The first review should be at 6 months after dose stabilisation and thereafter at 12 monthly intervals for continued therapy.
- Undertake monitoring as described in the shared care guideline including annual thyroid function test.

- Prompt communication with GP of any changes in treatment, results of monitoring undertaken and assessment of adverse events.

- Advice to GP on when to stop treatment.

- Provide the GP with relevant contact information with clear arrangements for back-up advice and support should further assistance be required relating to this drug.

- Reporting adverse events to the MHRA.

2.8.4. **General Practitioner:**

- To respond to the shared care request from the consultant in writing without undue delay.

- Prescribing somatropin in particular BY BRAND after communication with specialists regarding the need for treatment (this will usually take place after the first 3 months of dose stabilisation).

- GP prescribing of somatropin or somatrogon for a further 9 months after dose stabilisation. At this point the consultant will review the patient to assess whether there is any benefit from continued treatment.

- Prompt referral to a specialist if there is symptomatic change in the patient's expected response to treatment.

- Reporting to, and seeking advice from, a specialist on any aspect of patient care which is of concern to the GP and may affect treatment.

- Reporting adverse events to the specialist and MHRA.

- Stopping treatment in the case of severe adverse event or as per shared care guideline.

2.8.5. **Patient / parent / guardian / carer:**

- Report any adverse effects to their GP and/or specialist regarding their treatment.

- Ensure that they have a clear understanding of their treatment.

- Ensure they attend for monitoring requirements as per shared care guideline.

- Aware that treatment will be stopped if patient does not attend for monitoring.

2.8.6. **BACK-UP ADVICE AND SUPPORT IS AVAILABLE FROM THE RELEVANT CLINICAL TEAM.**

3. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Compliance with prescribing and administration in accordance with this guideline (or other safe practice).
Lead	Head of Prescribing Support Unit.
Tool	Audit and review tool using patient documentation.
Frequency	As required according to clinical incident reports.
Reporting arrangements	Via Cornwall Area Prescribing Committee / Medication Practice Committee.
Acting on recommendations and Lead(s)	Relevant Clinical Staff.
Change in practice and lessons to be shared	Lessons and changes in practice will be communicated through various channels to relevant staff.

4. Equality and Diversity

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the Equality Diversity And Inclusion Policy or the Equality and Diversity website.

4.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Growth Hormone (Somatropin and Somatrogon) for Paediatric Use Shared Care Guideline V3.1
This document replaces (exact title of previous version):	Growth Hormone (Somatropin) for Paediatric Use Shared Care Guideline V3.0
Date Issued/Approved:	May 2023
Date Valid From:	May 2023
Date Valid To:	November 2025
Directorate / Department responsible (author/owner):	Paediatric Team / Pharmacy - Head of Prescribing Support Unit
Contact details:	01872 253548
Brief summary of contents:	Some clinical issues and details of prescribing responsibilities for GP and specialists
Suggested Keywords:	Somatropin, growth hormone
Target Audience:	**RCHT:** Yes **CFT:** No **CIOS ICB:** Yes
Executive Director responsible for Policy:	Chief Medical Officer
Approval route for consultation and ratification:	Cornwall Area Prescribing Committee
General Manager confirming approval processes:	Richard Andrzejuk
Name of Governance Lead confirming approval by specialty and care group management meetings:	Kevin Wright
Links to key external standards:	None required
Related Documents:	Resource for Doctors and Patients: http://www.pituitary.org.uk Summary of Product Characteristics.

Information Category	Detailed Information
	NICE Technology Appraisal 188: Human growth hormone (somatropin) for the treatment of growth failure in children (published May 2010) NICE Technology Appraisal 863: Somatrogon for treating growth disturbance in children and young people aged 3 years and over (published February 2023) BSPED Shared Care Guideline (endorsed May 2012 and reviewed July 2015)
Training Need Identified?	No
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Clinical / Pharmacy

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
June 14	V1.0	Original document	M Wilcock, Head of Prescribing Support Unit
May 17	V1.1	Minor amendments	M Wilcock, Head of Prescribing Support Unit
Sept 19	V2.0	New format and inclusion of shared care agreement letter	M Wilcock, Head of Prescribing Support Unit
March 2020	V2.1	Appendix 3 added following FRG approval - CHA4215 Shared Care Agreement Letter Consultant Request	Demi Louise Kent, Corporate records Manager
Sept 2021	V2.2	Replacement of Shared Care Agreement Letter with suggested wording template instead (Appendix 3)	M Wilcock, Head of Prescribing Support Unit
Nov 2022	V3.0	Minor text amendment at 2.3.2	M Wilcock, Head of Prescribing Support Unit
May 2023	V3.1	Inclusion of somatrogon product and relevant text	M Wilcock, Head of Prescribing Support Unit

All or part of this document can be released under the Freedom of Information Act 2000

All Policies, Strategies and Operating Procedures, including Business Plans, are to be kept for the lifetime of the organisation plus 6 years.

This document is only valid on the day of printing.

Controlled Document

This document has been created following the Royal Cornwall Hospitals NHS Trust The Policy on Policies (Development and Management of Knowledge Procedural and Web Documents Policy). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity and Inclusion Team rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	Growth Hormone (Somatropin and Somatrogon) for Paediatric Use Shared Care Guideline V3.1
Directorate and service area:	Pharmacy
Is this a new or existing Policy?	Existing
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Dan Thomas, Pharmaceutical Services Contracting Team, NHS Kernow
Contact details:	01726 627953

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	To provide information on prescribing of somatropin (growth hormone) to enable General Practitioners to take over prescribing responsibility from secondary care.
2. Policy Objectives	To promote a consistent level of shared care between primary and secondary care (in relation to RCHT catchment area).
3. Policy Intended Outcomes	Confident and competent prescribers, enabling medicines to be access in a primary care setting.
4. How will you measure each outcome?	Six monthly review.
5. Who is intended to benefit from the policy?	General practitioners, hospital specialists and community pharmacists – from understanding local guidance around use of these medicines. Patients/carers, from being able to access medicines from their GP.

Information Category	Detailed Information
6a. Who did you consult with? (Please select Yes or No for each category)	• Workforce: Yes • Patients/ visitors: No • Local groups/ system partners: No • External organisations: No • Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	**Please record specific names of individuals/ groups:** Cornwall Area Prescribing Committee.
6c. What was the outcome of the consultation?	Agreed.
6d. Have you used any of the following to assist your assessment?	**National or local statistics, audits, activity reports, process maps, complaints, staff or patient surveys:** No.

7. The Impact
Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	No	
Sex (male or female)	No	
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	
Race	No	
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	
Religion or belief	No	
Marriage and civil partnership	No	

Protected Characteristic	(Yes or No)	Rationale
Pregnancy and maternity	No	
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment: Dan Thomas, Pharmaceutical Services Contracting Team, NHS Kernow

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis

Appendix 3. Suggested wording for Specialist communication re commencement of shared care

This patient is suitable for treatment with (insert drug name) for the treatment of (insert indication) which has been accepted for Shared Care. I am therefore requesting your agreement to share the care of this patient, as they are now stable on the treatment. Where baseline investigations are set out in the shared care protocol, I have carried these out.

Treatment was started on (insert date started) (insert dose).

If you are in agreement, please undertake monitoring and treatment from (insert date). (please note: date must be at least 1 month from stabilisation of treatment.)

Baseline tests: (insert information)

Next review with this department: (insert date)

You will be sent a written summary within (XX) days. The medical staff of the department are available at all times to give you advice. The patient will not be discharged from out-patient follow-up while taking (insert drug name).

Please could you reply to this request for shared care and initiation of the suggested medication to either accept or decline within 14 days.