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Royal Cornwall Hospitals NHS Trust

Somatropin in Adults Shared Care Guideline

V4.0

April 2022

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 Somatropin (growth hormone) when used in adults.

1.2. The Society for Endocrinology estimates that the prevalence of adult-onset GH deficiency is approximately 1 in 10,000 of the adult UK population.

1.3. 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. GH deficiency in adults may be associated with the following adverse features to a variable degree in any individual: reduced quality of life (QoL) especially reduced energy levels; altered body composition (reduced lean mass and increased fat mass, especially in the trunk); osteopenia/osteoporosis (reduced bone mineral density); dry skin (reduced sweating); reduced muscle strength and exercise capacity; lipid abnormalities (especially elevated LDL cholesterol); insulin resistance; increased levels of fibrinogen and plasminogen activator inhibitor; reduced extracellular fluid volume; increased thickness of the intima media of blood vessels; and impaired cardiac function.

1.4. Clinical studies have shown that growth hormone replacement therapy in such patients produces modest though significant improvements in these clinical features. However, they do not yet provide evidence that, for example, cardiac events or fracture rates are reduced as a consequence

1.5. This shared care guideline sets out details for the sharing of care of adults with growth hormone deficiency prescribed somatropin. These guidelines provide 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.

1.6. 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. Recommendant human growth hormone (somatropin) treatment is recommended for the treatment of adults with GH deficiency only if they fulfil all three of the following criteria:

- They have severe GH deficiency, defined as a peak GH response of less than 9 mU/litre (3 ng/ml) during an insulin tolerance test or a cross-validated GH threshold in an equivalent test.
- They have a perceived impairment of quality of life (QoL), as demonstrated by a reported score of at least 11 in the disease-specific 'Quality of life assessment of growth hormone deficiency in adults' (QoL-AGHDA) questionnaire.
- They are already receiving treatment for any other pituitary hormone deficiencies as required and these therapies have been optimized.
- NICE state the QoL status of people who are given GH treatment should be reassessed 9 months after initiation of therapy.

2.2. Patients who develop GH deficiency in early adulthood, after linear growth is completed but before the age of 25 years, should be given GH treatment until adult peak bone mass has been achieved, provided they satisfy the biochemical criteria for severe GH deficiency (defined as a peak GH response of less than 9 mU/litre (3 ng/ml) during an insulin tolerance test or a cross-validated GH threshold in an equivalent test). After adult peak bone mass has been achieved, the decision to continue GH treatment should be reassessed based on the three criteria.

2.3. 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.

2.4. **Preparations and Dosage**

2.4.1. Somatropin is human growth hormone produced by recombinant DNA technology. Its amino acid sequence is identical to that of natural human GH.

2.4.2. The Specialist Team will advise on the preparation to be used, with Omnitrope® as the first line growth hormone for adult patients.

2.4.3. Treatment is self-administered by a daily subcutaneous injection at bed-time. The initial dose is 150 micrograms (0.15mg) to 300 micrograms (0.3mg) daily [typically 270 micrograms (0.27mg) daily]. For the first 2-3 months the consultant/specialist nurse makes adjustments based on monthly assessments of serum IGF-I and appearance of adverse effects, until maintenance dose is achieved. The currently used median dose is 400 micrograms daily. Maximum daily dose is 1mg. GH requirements may decrease with age.

2.4.4. Somatropin 1mg ≡ 3 units (dose formerly expressed as units).

2.5. **Contraindications**

- Hypersensitivity to somatropin or any excipient of the formulation chosen.
- Evidence of tumour activity (complete any antitumour therapy and ensure that intracranial lesions are inactive before starting).
- After renal transplantation in seriously ill patients.
- Somatropin is not recommended during pregnancy and in women of childbearing potential not using contraception.
- Patients with acute critical illness (critically ill adult patients suffering complications following open heart surgery, abdominal surgery, multiple accidental trauma or acute respiratory failure).

2.6. **Precautions**

2.6.1. Diabetes mellitus (adjustment of antidiabetic therapy may be necessary).

2.6.2. Papilloedema.

2.6.3. History of malignant disease

2.6.4. Resolved intracranial hypertension (monitor closely).

2.6.5. Rotate subcutaneous injection sites to prevent lipoatrophy

2.6.6. Breast-feeding

2.6.7. Disorders of the epiphysis of the hip - monitor for limping

2.6.8. Pancreatitis should be considered in somatropin-treated patients who develop abdominal pain

2.6.9. Deficiencies of other pituitary hormones:

- ACTH deficiency – treatment with steroid replacement should precede other hormone replacement;
- Hypothyrodism – manufacturers recommend periodic <yearly> thyroid function tests but limited evidence of clinical value.

2.7. **Monitoring**

2.7.1. **Specialist Team:**

3.6.1.1. The consultant/specialist nurse is responsible for initial and ongoing assessment of the patient.

3.6.1.2. Adrenal deficiency should be assessed in the initial investigation and replacement therapy should be initiated before somatropin is considered.

3.6.1.3. Somatropin 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 6 months trial of therapy at a maintenance dose. GH treatment should be discontinued for those patients who demonstrate a QoL improvement of less than 7 points in QoL-AGHDA score at this time.

3.6.1.4. The consultant will carry out regular annual checks on haemoglobin A1c, blood glucose, insulin-like growth hormone (IGH-1) and thyroid function tests. Testing of luteinising hormone/follicle stimulating hormone will be patient dependent.

3.6.1.5. Insulin treated diabetes 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.

2.7.2. **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.

2.7.3. **Side Effects**

Most common adverse effects reported are

- Sodium retention (oedema, carpal tunnel syndrome) is only common with higher doses and can usually be relieved by a reduction in dose.
- Arthralgia and myalgia can occur but are also dose dependent and usually transient.
- Overtreatment with somatropin results in acromegaly.
- Other side effects include:
- Skin reactions at the injection site
- Hypothyroidism
- Hypertension
- Insomnia
- Headache (fundoscopy for papilloedema recommended if severe or recurrent)
- Visual problems

- Nausea and vomiting: if papilloedema is confirmed consider benign intracranial hypertension (rare cases reported)
- Myalgia
- Paraesthesia
- Antibody formation
- Hyperglycaemia
- Hypoglycaemia (causal link has not been established)

2.7.4. **Significant Drug Interactions**

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

3.6.1.7. **Oestrogens** – Higher doses of somatropin 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.

3.6.1.8. **Anticonvulsants and ciclosporin** – clearance of these compounds may be increased by somatropin 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 adult patients with growth hormone deficiency who are prescribed **somatropin** 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:**

- Confirmation that GH treatment is appropriate
- Selection of appropriate preparation and to teach the patient self-injection technique and how to dispose safely of any sharps / yellow bins
- 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/specialist nurse 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 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 for a further 6 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 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: and parent / carer responsibilities**

- 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

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, Inclusion & Human Rights 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:	Somatropin in Adults Shared Care Guideline V4.0
This document replaces (exact title of previous version):	Shared care guideline for somatropin in adults V3.2
Date Issued/Approved:	23 March 2022
Date Valid From:	April 2022
Date Valid To:	April 2025
Directorate / Department responsible (author/owner):	Endocrinology 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
Target Audience:	RCHT: Yes CFT: No KCCG: No
Executive Director responsible for Policy:	Medical Director
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
Related Documents:	No Resource for Doctors and Patients: http://www.pituitary.org.uk Summary of Product Characteristics. NICE Technology Appraisal 64: Human growth hormone (somatropin) in adults with growth hormone deficiency - August 2003.

Information Category	Detailed Information
Training Need Identified?	No
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet & Intranet
Document Library Folder/Sub Folder:	Clinical / Pharmacy

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
19 Sept 2012	V1.0	Initial Version	M Wilcock, Head of Prescribing Support Unit
23 Sept 2015	V2.0	New style Appendix and minor text alterations	M Wilcock, Head of Prescribing Support Unit
Nov 2018	V3.0	New format and slight text amendments 2.4, 2.7, 2.9 and inclusion of shared care agreement letter	M Wilcock, Head of Prescribing Support Unit
March 2020	V3.1	Appendix 3 added following FRG approval - CHA4215 Shared Care Agreement Letter Consultant Request	Demi Louise Kent, Corporate records Manager
Sept 2021	V3.2	Replacement of shared care agreement letter with suggested wording template (Appendix 3).	M Wilcock, Head of Prescribing Support Unit
March 2022	V4.0	Correction of minor typos	M Wilcock, Head of Prescribing Support Unit

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

This document is to be retained for 10 years from the date of expiry.
This document is only valid on the day of printing

Controlled Document

This document has been created following the Royal Cornwall Hospitals NHS Trust Policy for the Development and Management of Knowledge, Procedural and Web Documents (The Policy on Policies). 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 & Inclusion Team rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	Somatropin in Adults Shared Care Guideline V4.0
Directorate and service area:	Pharmacy, Clinical Support
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 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.