One + all | we care

Royal Cornwall Hospitals NHS Trust

Somatropin in Adults Shared Care Guideline

V3.0

February 2018

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.
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.

1.3. 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

1.4. 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.

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

The Trust has a duty under the DPA18 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 can’t rely on Opt out, it must be Opt in.

The DPA18 covers how the Trust obtains, hold, record, use and store all personal and special category (e.g. Health) information in a secure and confidential manner. This Act covers all data and information whether held electronically or on paper and extends to databases, videos and other automated media about living individuals including but not limited to Human Resources and payroll records, medical records, other manual files, microfilm/fiche, pathology results, images and other sensitive data.

DPA18 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the DPA18 please see the 'information use framework policy', or contact the Information Governance Team rch-tr.infogov@nhs.net

2. The Guidance

2.1. Recombinant 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 to 300 micrograms daily (typically 270 micrograms 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 in critical care are not recommended growth hormone.

2.6. Precautions

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

- Papilloedema.

2.6.1. 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.

- History of malignant disease.

- Resolved intracranial hypertension (monitor closely).

- Rotate subcutaneous injection sites to prevent lipoatrophy.

- Breast-feeding.

2.7. Monitoring

2.7.1. Specialist Team:

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

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

2.7.1.3. 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 that 7 points in QoL-AGHDA score at this time.

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

2.7.1.5. 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 hypothyroidsm is suspected or identified.

2.7.3. Side Effects

Most common adverse effects reported are oedema, arthralgia and carpal tunnel syndrome. These effects are dose-related and transient, usually subsiding if the dose is reduced. 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

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

2.7.4.2. **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.

2.7.4.3. **Anticonvulsants and ciclosporin** – clearance of these compounds may be increased by somatropin resulting in lower plasma levels of these compounds.

2.8.1. Handling and Disposal

The contents of capsules should not be inhaled or allowed to come into contact with the skin or mucous membranes. Spillages must be wiped immediately. Capsules should only be handled by the patient taking them.

2.8. References:

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.

2.9. Areas of Responsibility for the Sharing of Care

2.9.1. 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.

2.9.2. 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.

2.9.3. 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 shared care agreement letter

 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

2.9.4. General Practitioner:

 If the GP disagrees to undertake shared care he/she will notify the consultant in writing without undue delay by completing the shared care agreement letter

 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

2.9.5. Patient: and parent / carer responsibilities

 Sign the shared care agreement letter

 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

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	No specific tool
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

Document Title	Somatropin in Adults Shared Care Guideline V3.0					
Date Issued/Approved:	November 2018					
Date Valid From:	February 2019					
Date Valid To:	February 2022					
Directorate / Department responsible (author/owner):	Cancer 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	CFT	KCCG			
	✓		✓			
Executive Director responsible for Policy:	Medical Director					
Date revised:	Nov'18					
This document replaces (exact title of previous version):	Shared care guideline for somatropin in adults					
Approval route (names of committees)/consultation:	Cornwall Area Prescribing Committee					
Divisional Manager confirming approval processes	Karen Jarvill					
Name and Post Title of additional signatories	Not required					
Name and Signature of Divisional/Directorate Governance Lead confirming approval by specialty and divisional management meetings	{Original Copy Signed}					
	Name: Kevin Wright					
Signature of Executive Director giving approval	{Original Copy Signed}					
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet & Intranet	✓	Intranet Only			

Document Library Folder/Sub Folder	Pharmacy
Links to key external standards	None indicated
Related Documents:	None indicated
Training Need Identified?	No

Governance Information

Version Control Table

Date	Version No	Summary of Changes	Changes Made by *(Name and Job Title)*
19 Sept 2012	V1.0		M Wilcock, Head of Prescribing Support Unit
23 Sept 2015	V 2.0	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

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. Initial Equality Impact Assessment Form

This assessment will need to be completed in stages to allow for adequate consultation with the relevant groups.

<table>
<tr><td colspan="6">Somatropin in Adults Shared Care Guideline V3.0</td></tr>
<tr><td colspan="3">Directorate and service area:
Pharmacy</td><td colspan="3">Is this a new or existing Policy:
Existing</td></tr>
<tr><td colspan="3">Name of individual completing assessment:
Dan Thomas, Pharmaceutical Services Contracting Team, NHS Kernow</td><td colspan="3">Telephone:
01726 627953</td></tr>
<tr><td>1. Policy Aim*

Who is the strategy / policy / proposal / service function aimed at?</td><td colspan="5">To provide information on prescribing of somatropin to enable General Practitioners to take over prescribing responsibility from secondary care.</td></tr>
<tr><td>2. Policy Objectives*</td><td colspan="5">To promote a consistent level of shared care between primary and secondary care (in relation to RCHT catchment area)</td></tr>
<tr><td>3. Policy – intended Outcomes*</td><td colspan="5">Confident and competent prescribers, enabling medicines to be access in a primary care setting.</td></tr>
<tr><td>4. *How will you measure the outcome?</td><td colspan="5">Six monthly review</td></tr>
<tr><td>5. Who is intended to benefit from the policy?</td><td colspan="5">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.</td></tr>
<tr><td rowspan="3">6a Who did you consult with

b). Please identify the groups who have been consulted about this procedure.</td><td>Workforce</td><td>Patients</td><td>Local groups</td><td>External organisations</td><td>Other</td></tr>
<tr><td>X</td><td></td><td>X</td><td></td><td></td></tr>
<tr><td colspan="5">Please record specific names of groups
Cornwall Area Prescribing Committee</td></tr>
<tr><td>What was the outcome of the consultation?</td><td colspan="5">Agreed</td></tr>
</table>

7. The Impact
Please complete the following table. **If you are unsure/don't know if there is a negative impact you need to repeat the consultation step**.

Are there concerns that the policy **could** have differential impact on:

Equality Strands:	Yes	No	Unsure	Rationale for Assessment / Existing Evidence
Age		**X**		
Sex (male, female, trans-gender / gender reassignment)		**X**		
Race / Ethnic communities /groups		**X**		
Disability - Learning disability, physical impairment, sensory impairment, mental health conditions and some long term health conditions.		**X**		
Religion / other beliefs		**X**		
Marriage and Civil partnership		**X**		
Pregnancy and maternity		**X**		
Sexual Orientation, Bisexual, Gay, heterosexual, Lesbian		**X**		

You will need to continue to a full Equality Impact Assessment if the following have been highlighted:

- You have ticked "Yes" in any column above and
- No consultation or evidence of there being consultation- this excludes any *policies* which have been identified as not requiring consultation**. or**
- Major this relates to service redesign or development

8. Please indicate if a full equality analysis is recommended.	**Yes**		**No X**	

9. If you are **not** recommending a Full Impact assessment please explain why.

Not indicated

Signature of policy developer / lead manager / director Mike Wilcock		Date of completion and submission November 2018
Names and signatures of members carrying out the Screening Assessment	1. M Wilcock 2. Human Rights, Equality & Inclusion Lead	

Keep one copy and send a copy to the Human Rights, Equality and Inclusion Lead
c/o Royal Cornwall Hospitals NHS Trust, Human Resources Department, Knowledge Spa, Truro, Cornwall, TR1 3HD

This EIA will not be uploaded to the Trust website without the signature of the Human Rights, Equality & Inclusion Lead.

A summary of the results will be published on the Trust's web site.

Signed M Wilcock

Date 28/11/18