

THE SHEFFIELD AREA PRESCRIBING GROUP

Shared Care Guideline

For

The treatment of Adults with Growth Hormone (Somatropin)

Shared Care Prescribing guideline developed by:

**Professor John Newell-Price, Consultant Endocrinologist, STHFT
Victoria Ibbotson, Endocrinology Specialist Nurse, STHFT
Sallianne Kavanagh, Lead Pharmacist Diabetes and Endocrinology, STHFT
Sharron Kebell, Specialised Commissioning Pharmacist, Sheffield CCG**

Date approved: March 2018

Review Date: 3 years from approval

Shared Care Guideline for the Treatment of Adults with Growth Hormone (Somatropin)

Statement of Purpose

This shared care guideline has been written to enable the continuation of care by primary care clinicians of patients initiated on recombinant human growth hormone by specialist endocrinologists at Sheffield Teaching Hospital NHS Foundation Trust. Primary care will only be requested to take over prescribing of growth hormone therapy within its licensed indication unless specifically detailed otherwise below.

Responsibilities of consultant clinician

- Undertake necessary testing to confirm diagnosis and prescribe in line with NICE TA64
- To discuss benefits and side effects of treatment with the patient/carer and obtain informed consent.
- Provide written information to patients and their carers about their condition and treatment
- To initiate somatropin (Omnitrope®) in appropriate patients
- To discontinue therapy if side effects pose a clinical risk to the patient
- To train patients and families to self-administer GH injections,
- To monitor the patient as described below
- To prescribe the first nine month's supply or until patient stable
- To prescribe / supply sharp bin for safe disposal of needles / devices
- To contact patient's GP to request prescribing in line with this shared care prescribing guideline and send a link to or copy of the guideline
- To advise the GP regarding continuation of treatment
- To discuss any concerns with the GP regarding the patient's therapy
- The patient is to remain under the consultants care whilst ever the patient is being prescribed somatropin

Responsibilities of the primary care clinician

- To refer appropriate patients to secondary care for assessment
- To agree to prescribe for patients in line with the shared care prescribing guideline
- To report any adverse reaction to the MHRA and the referring consultant
- To continue to prescribe for the patient as advised by the consultant
- To prescribe sharp bin for safe disposal of needles / devices
- To inform the consultant if the patient discontinues treatment for any reason
- To seek the advice of the consultant if any concerns with the patient's therapy
- To conduct an annual medication review or more frequent if required
- In the event that the GP is not able to prescribe, or where the shared care is agreed but the consultant is still prescribing certain items e.g. Hospital only product; the GP will provide the consultant with full details of existing therapy promptly by fax on request
- For medication supplied from another provider GPs are advised to follow recommendations for Recording Specialist initiated Drugs on Clinical Practice Systems

This is guidance on the management of a condition not a commissioning arrangement

- http://www.intranet.sheffieldccg.nhs.uk/Downloads/Medicines%20Management/Practice%20resources%20and%20PGDs/Recording_SIDs_on_practice_clinical_systems%20.pdf

Patient/Parent Responsibilities

- To ensure they have clear understanding of the prescribed treatment.
- To administer the GH as directed by the supervising consultant; attend clinic and GP reviews as requested.
- To share any concerns in relation to treatment with the supervising consultant and/or GP.
- To report any adverse effects to the supervising consultant and/or GP whilst taking GH.
- To attend any appointments for monitoring purposes

Indication

Somatropin is a potent metabolic hormone of importance for the metabolism of lipids, carbohydrates and proteins. It is recommended for the treatment of adults with growth hormone (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.

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 as mentioned above. After adult peak bone mass has been achieved, the decision to continue GH treatment should be based on all of the aforementioned three criteria.

Nine months after the initiation of therapy (an initial 3-month period of GH dose titration, followed by a 6-month therapeutic trial period) and ongoing monitoring, patients are reassessed and GH is only continued in those patients who demonstrate a QoL improvement of more than 7 points in QoL-AGHDA score.

NICE technology appraisal TA64 Human growth hormone (somatropin) in adults with growth hormone deficiency can be found using the following link:

<https://www.nice.org.uk/guidance/ta64>

Selection of patients

Specialist endocrinologists at STHFT will assess patients as per NICE guidance (TA64) and start treatment as appropriate for patients that meet the aforementioned criteria.

Dosage

It has been agreed that the biosimilar version of somatropin (Omnitrope®) will be prescribed in Sheffield as this is less expensive than other brands of somatropin. Patients will be assessed and depending on their dexterity and whether they have any visual impairment issues, a decision will be made to initiate or switch to Omnitrope®. The following provide an opportunity to review patient's somatropin :

- All new patients starting on somatropin
- All patients transitioning to the adult service
- At annual review of existing patients by secondary care

Treatment is self-administered by a daily subcutaneous injection.

Initial dose of 0.15 - 0.3 mg daily. The dose should be gradually increased after monthly assessments of serum levels of IGF-I and in response to the presence of adverse effects, until a maintenance dose is achieved. The maintenance dose rarely exceeds 1 mg per day. Dose requirements may decrease with age.

N.B. Although Omnitrope® is the first line choice of somatropin, this guideline does not exclude prescription of other brands of somatropin if patients are clinically assessed and other preparations are considered more suitable.

Contra-indications

Hypersensitivity to the active substance or to any of the excipients.

Any evidence of activity of a tumour. Intracranial tumours must be inactive and antitumour therapy must be completed prior to starting growth hormone therapy. Treatment should be discontinued if there is evidence of tumour growth.

Patients with acute critical illness suffering complications following open heart surgery, abdominal surgery, multiple accidental trauma, acute respiratory failure or similar conditions should not be treated with somatropin.

Pregnancy and Lactation

Somatropin is not recommended during pregnancy and in women of childbearing potential not using contraception. It is also not recommended during lactation.

Monitoring

The specialist Endocrinology team will be responsible for the monitoring of r-hGH therapy, which includes:

- Assess the patient and establish the need for somatropin with provision of appropriate information on GH deficiency and its treatment
- Initiate treatment and titrate the dose based on IGF-1 levels including review of patient at monthly intervals for first 3 months
- Assessment of quality of life by disease specific questionnaire (QOL-AGHDA) at 9 months

This is guidance on the management of a condition not a commissioning arrangement

- Clinical and laboratory supervision at 6-12 month intervals, including assessment of weight (BMI), blood pressure, HbA1c, thyroid function tests (TFTs), lipid profile, IGF-1, clinical assessment of general health while patient remains on somatropin

Side –effects

The summary of product characteristics for somatropin states that side effects include headache, visual problems, nausea and vomiting, fluid retention (peripheral oedema), arthralgia, myalgia, carpal tunnel syndrome, paraesthesia, antibody formation, hypothyroidism and reactions at injection site.

Adverse event	Action to be taken	By whom
Headache: If severe, recurrent, or associated with nausea and vomiting	Report immediately to the Specialist Endocrine Dept. Somatropin to be discontinued	GP or named Specialist Endocrinologist/Endocrinology Team
Signs of fluid retention: Such as peripheral oedema, stiffness in the extremities, arthralgia, myalgia and paraesthesia are common when starting somatropin	Usually mild to moderate and subsides spontaneously or with dose reduction. Discuss if persistent or severe paraesthesia present. Dose reduction may be necessary to avoid the development of carpal tunnel syndrome	GP or named Specialist Endocrinologist/Endocrinology Team
Lipoatrophy: May occur at site of injection	This can be avoided by varying the site of administration	Patient to be educated on this aspect at the time of GH initiation by the Specialist Endocrinology Team
Insulin resistance: Diabetic patients on insulin may require increased insulin requirements	HbA1c should be monitored and patients advised accordingly	Named Specialist Endocrinologist/Endocrinology & Diabetes Team or GP
Hypothyroidism: Has been observed with somatropin	Thyroid function should be monitored	Named Specialist Endocrinologist/Endocrinology Team

The above details are not a complete list and the BNF and the SPC remain authoritative.

Stopping treatment

The decision to stop treatment should be made in consultation with the patient and/or carers by the Consultant Endocrinologist. See information under indication section for further details.

Interactions

Corticosteroids – growth promoting effect may be inhibited

Oestrogens – increased doses of somatropin may be required

This is guidance on the management of a condition not a commissioning arrangement

CYP3A4 – somatropin is predicted to increase the clearance of drugs metabolised by CYP3A4 and could potentially result in lower plasma levels of drugs such as anticonvulsants, sex steroids and ciclosporin

Insulin – somatropin may reduce the efficacy of insulin. For patients with diabetes mellitus, the insulin dose may require adjustment after somatropin therapy is instituted. Patients with diabetes, glucose intolerance, or additional risk factors for diabetes should be monitored closely during somatropin therapy.

The above details are not a complete list and the current BNF and the [SPC](#) remain authoritative.

Additional information

Omnitrope® should be stored and transported refrigerated (2°C - 8°C) and should not be frozen. To minimise injection site reactions it is recommended that it is stored at room temperature for at least 30 minutes before administration. Cartridges have a shelf-life of 28 days.

For other prescribed brands of growth hormone please refer to the SPC at www.medicines.org.uk for specific storage information.

Re-Referral guidelines

Contact the Endocrinology Team if there are any concerns about patient adherence (e.g. prescriptions not being requested or collected).

Transition from Children's Service

From the age of 18 years, patients will be transferred to the adult service in Sheffield and this may mean that patients are changed from their current brand of somatropin to Omnitrope®.

Financial implications

The biosimilar version of somatropin (Omnitrope®) is approximately 20% cheaper than other brands of somatropin and so is recommended for use, see under dose section of SCG.

Support, education and information

Endocrinology Team at STHFT:

Professor J Newell-Price, Consultant Endocrinologist
Victoria Ibbotson Specialist Endocrinology Nurse

Telephone: 0114 27172425 or 0114 2713714

References

<https://bnf.nice.org.uk/>

Human growth hormone (somatropin) for the treatment of growth failure in adults -

<https://www.nice.org.uk/guidance/ta64/resources/human-growth-hormone-somatropin-in-adults-with-growth-hormone-deficiency-pdf-2294698052293>

A full list of side-effects is given in the summary of product characteristics (SPC) for each product is available from www.emc.medicines.org.uk .

This is guidance on the management of a condition not a commissioning arrangement