Barking and Dagenham, Havering & Redbridge Clinical Commissioning Groups and Barking, Havering & Redbridge University Hospitals Trust Shared Care Guidelines

DRUG NAME: SOMATROPIN

Shared Care Guidelines for the use of Human Growth Hormone (Somatropin) in Adults with Growth Hormone Deficiency in accordance with NICE TA 64 (2003)

DOCUMENT TO BE SCANNED INTO ELECTRONIC RECORDS AS AND FILED IN NOTES

Patient Name: **Date of Birth:** **NHS No:**

Name of Referring Consultant: **Contact number:**

INTRODUCTION – Indication and Licensing

Growth hormone is normally produced by the pituitary gland, which lies at the base of the brain. Naturally occurring human growth hormone is also called somatotrophin. It helps to control the body's use of proteins, carbohydrates and lipids. Growth hormone is also involved in the growing process in children, as it has an effect on the growth of bones.

Growth hormone deficiency is the term used when the amount of growth hormone produced is much lower than usual. In adults, growth hormone deficiency can happen as a result of damage to the pituitary gland or to the part of the brain called the hypothalamus, which is closely linked to the pituitary. Such damage can be caused by a tumour in the area or by the treatment the person had for the tumour (surgery or radiotherapy). Growth hormone deficiency can also happen if there has been a problem with the blood supply to the pituitary or hypothalamus.

It is possible to replace the missing growth hormone by having regular injections of human growth hormone. Growth hormone of human origin (HGH; somatrophin) has been replaced by a growth hormone of human sequence, **somatropin**; produced using recombinant DNA technology.

Indication:

NICE recommends **Somatropin** (Recombinant Human Growth Hormone) for use in adults if the following 3 criteria are fulfilled:

- Severe growth hormone deficiency, established by an appropriate method
- Impaired quality of life, measured by means of a specific questionnaire
- Already receiving treatment for another pituitary hormone deficiency

Treatment with somatropin should be initiated and managed by a physician with expertise in growth hormone disorders; maintenance treatment can be prescribed in the community under a shared care protocol.

PATIENT PATHWAY

Indication	Prescribing Initiated by:	Prescribing Continued by:	Monitored by:	Duration of treatment
Severe growth hormone deficiency: as specified by NICE TA 64. See above (under the heading "Indication")	BHRUT Consultant Endocrinologists with expertise in growth hormone disorders	Suitable for transfer to General Practitioner (GP) once maintenance dose established. GP may prescribe after 3 months but may not titrate doses.	BHRUT Specialist Nurse for Endocrinology with expertise in growth hormone disorders. Monitored monthly in hospital for first 3 months, then every 3 – 6 months depending on response and titration.	Dependent on age and underlying conditions (See below for details)

Review of outcome to be assessed by Consultant Endocrinologist or Specialist Endocrine Nurse at BHRUT. Duration of Somatropin treatment dependent on age and underlying conditions as detailed below:

- Somatropin treatment should be discontinued if the quality of life has not improved sufficiently by 9 months.
- Severe growth hormone deficiency developing after linear growth is complete but before the age of 25 years should be treated with growth hormone; treatment should continue until adult peak bone mass has been achieved.
- Treatment for adult-onset growth hormone deficiency should be stopped only when the patient and the patient's physician consider it appropriate.

Growth hormone deficiency in adults is a life long disease and needs to be treated accordingly, however experience in patients over 60 years and in patients with more than five years treatment in adult growth hormone deficiency is still limited. Current prcatice

DOSE AND ADMINISTRATION

Usual regime for adult growth hormone deficiency:

- Administration by subcutaneous injection, dose initially 150-300micrograms daily, gradually increased if required to maximum 1mg daily in the evening; use minimum effective dose (requirements may decrease with age)
- Recommended gradual dose increases at monthly intervals based on the clinical response and the patient's experience of adverse events
- The site of administration should be varied to prevent lipoatrophy

MONITORING STANDARDS FOR MEDICATION AT BHRUT

Monitoring to take place by BHRUT Specialist Endocrinology Consultant / Nurse

Parameter	IGF-I (insulin-like growth factor)
Target level	No standard reference range (age related range ng/ml)
Frequency of monitoring	Variable to individual patient (monthly – annual)
Action	Dose titration as appropriate according to response

KEY ADVERSE EFFECTS & ACTIONS

Adverse effects	**Symptoms/signs**	**Actions** (for *GP take if identified in primary care)*
Reactions at injection site	Lipoatrophy	Injection site inspection and site rotation advice/counselling
Raised Intracranial Pressure (ICP)	Severe recurrent headache, visual problems, nausea and vomiting	Funduscopy recommended. If raised ICP confirmed: consider benign intracranial hypertension (rare cases reported) and refer back to hospital specialist.
Relative deficiencies of other pituitary hormones	Hypothyroidism symptoms In diabetes mellitus: insulin resistance, hyperglycaemia	Adjustment of anti diabetic therapy may be necessary as somatropin may reduce insulin sensitivity
Fluid retention Arthralgia, myalgia, carpal tunnel syndrome, paraesthesia, antibody formation	Peripheral oedema Musculoskeletal pain, pains and numbness on fingers/wrist CNS disorders	Contact hospital Endocrinology Consultants with expertise in growth hormone disorders

This only lists the key important ADRs - For comprehensive information on cautions, contra-indications and interactions please refer to the <u>current</u> British National Formulary and Summary of Product Characteristics.

Caution: Women may require higher doses than men, with men showing an increasing IGF-I sensitivity over time. This means that there is a risk that women, especially those on oral oestrogen replacement are under-treated while men are over-treated

<u>Contra-indications</u>: evidence of tumour activity (complete anti tumour therapy and ensure intracranial lesions inactive before starting; not to be used after renal transplantation). Also, patients with acute critical illness suffering complications following open heart surgery, abdominal surgery, multiple accidental trauma, acute respiratory failure should not be treated with somatropin.

PREGNANCY AND BREAST FEEDING

No clinical data on exposed pregnancies is available and it is not known whether somatropin is excreted in human milk.
If pregnancy occurs: Refer to antenatal clinic immediately (joint antenatal and endocrine clinic).

For comprehensive information please refer to the current British National Formulary and Summary of Product Characteristics.

SHARED CARE

Shared care guideline*:* is a document which provides information allowing patients to be managed safely by primary care, secondary care and across the interface. It assumes a partnership and an agreement between a hospital specialist, GP and the patient and also sets out responsibilities for each party. The intention to shared care should be explained to the patient and accepted by them. Patients are under regular follow-up and this provides an opportunity to discuss drug therapy. Intrinsic in the shared care agreement is that the prescribing doctor should be appropriately supported by a system of communication and cooperation in the management of patients. The doctor who prescribes the medicine has the clinical responsibility for the drug and the consequence of its use**.**

Responsibilities of Hospital and Consultant Endocrinologist

1. Ensure that the patient understands the nature, effect and potential side effects of the drug before prescribing it as part of the shared care programme and provide clarification where appropriate.
2. Ensure that the patient/carer is an informed recipient of growth hormone therapy.
3. Ensure that the patient understands their treatment regimen and any monitoring or follow up that is required (using advocacy if appropriate). Issue any local patient information leaflets where appropriate.
4. Initiate treatment and prescribe until the GP formally agrees to share care (as a minimum, supply the first 3 months of treatment or until patient is stabilised).
5. Send a letter to the GP requesting shared care for this patient.
6. Clinical and laboratory supervision of the patient by blood monitoring and routine clinic follow-up on a regular basis.
7. Send a letter/results notification to the GP after each clinic attendance ensuring current dose, most recent blood results and frequency of monitoring are stated (unless otherwise covered by letter from Endocrine Nurse Specialist).
8. Evaluation of any reported adverse effects by GP or patient.
9. Advise GP on review, duration or discontinuation of treatment where necessary. Where urgent action is required following tests the hospital team will telephone the patient and inform GP.
10. Inform GP of patients who do not attend clinic appointments.
11. Ensure suspected adverse drug reactions are appropriately reported via the yellow card scheme to MHRA.

Responsibilities of General Practitioner in the Community

1. Monitor patients overall health and well-being.
2. Report any adverse events to the consultant, where appropriate.
3. Report any adverse events to the MHRA, where appropriate.
4. Prescribe the drug treatment as described.

CCG

1. To provide feedback to trusts via Trust Medicines Committee.
2. To support GPs to make the decision whether or not to accept clinical responsibility for prescribing.
3. To support trusts in resolving issues that may arise as a result of shared care.

Patient/Carer

1. Administer the medication as prescribed and as agreed.
2. Report any adverse effects to their GP and/or specialist.
3. Ensure they have a clear understanding of their treatment.
4. Report any changes in disease symptoms to GP and/or specialist.
5. Alert GP and/or specialist of any changes of circumstance which could affect management of disease e.g. plans for pregnancy.
6. Undertake any monitoring as requested by the GP and/or specialist.

Costs (Bold items most commonly prescribed in order of selection preference):

Drug Product	Cost in primary care (For 1 month course): Prices as per BNF 66 (September 2013 – March 2014)
Omnitrope® (Sandoz) To be stored in the fridge at all times	**Injection 3.3mg (10units/mL) -1.5mL (5mg, 15 unit) cartridge = £86.76 +VAT** Injection 6.7mg (20units/mL) -1.5mL (10mg, 30 unit) cartridge = £182.66 +VAT
Norditropin® (Novo Nordisk) Stable at room temperature for 21days. Stable for 4 weeks if	**SimpleXx® injection 3.3mg (10 units/mL) -1.5mL (5mg, 15 unit) cartridge = £106.35 +VAT** SimpleXx® injection 6.7mg (20 units/mL) -1.5mL (10mg, 30 unit) cartridge = £212.70 +VAT SimpleXx® injection 10mg (30 units/mL) – 1.5mL (15mg, 45 unit) cartridge = £319.05 +VAT

kept in fridge once open	NordiFlex® injection 10mg (30 units/mL) – 1.5mL (15mg, 45 unit) cartridge = £347.70 +VAT
NutropinAq® (Ipsen) (only prescribed when Omnitrope® and Norditropin® out of stock / unavailable	10mg (30 units) 2ml cartridge = £203.00 +VAT
Saizen® (Merk Serono) Rarely / never prescribed for adults	Injection 5.83mg (17.5 units/mL) – 1.03mL (6mg, 18 unit) cartridge = £139.08 +VAT Injection 8mg (24 units/mL) – 1.5mL (12mg, 36 unit) cartridge = £278.16 +VAT Injection 12mg (36 units/mL - 2.5mL (20mg, 60 unit) cartridge = £463.60 +VAT Click.easy® powder for reconstitution 8mg (24 unit) vial with diluent = £185.44 +VAT

RESOURCES AVAILABLE

Barking, Havering and Redbridge University NHS Trust	
Consultant Endocrinologists: QH - Dr N Stojanovic QH - Dr E Marouf QH - Dr B Hossain QH - Dr F Nkonge KGH-Dr E Casey KGH-Dr K Nikookam Registrar on-call out of hours	Queens Hospital (switchboard): 01708 435000 then: Secretary Extension Number: 3817 Secretary Extension Number: 2176 Secretary Extension Number: 2176 Secretary Extension Number: 2176 King George Hospital (switchboard): 0208 983 8000 then: Secretary Extension Number: 8040 Secretary Extension Number: 8040 Aircall via switchboard
Endocrine Nurse Specialist: Anna Hawkins	King George Hospital (switchboard): 0208 983 8000 Extension: 8346
Endocrinology Pharmacist: Gurjit Gondal	King George Hospital (switchboard): 0208 983 8000 Extension: 8394
BHR CCGs Medicines Management Team	0208 822 3074 or 0208 822 3076 Fax. 0208 926 5423

References

1. National Institute for Clinical Excellence TA64: The use of human growth hormone (somatropin) for adults with growth hormone deficiency, August 2003. (www.nice.org.uk/TA64)
2. British National Formulary 66: Section 6.5.1, September 2013 – March 2014 (www.bnf.org)
3. Summary of product characteristics (SPC) for Somatropin by brands available:
   (Omnitrope® (Sandoz), Norditropin® (Novo Nordisk), NutropinAq® (Ipsen), Saizen® (Merk Serono)

Refer to the relevant BHR CCG website to obtain the latest version of this guideline

http://www.barkingdagenhamccg.nhs.uk/About-us/Medicines-management/shared-care-guidelines.htm
http://www.haveringccg.nhs.uk/About-us/medicines-management/shared-care-guidelines.htm
http://www.redbridgeccg.nhs.uk/About-us/Medicines-management/shared-care-guidelines.htm

Recommended Patient Help Groups:

The Pituitary Foundation
PO Box 1944, Bristol BS99 2UB
Tel/Fax 08707743355
Email: helpline@pituatry.org.uk

Barking, Havering and Redbridge University NHS Trust (BHRUT)

SOMATROPIN IN ADULTS SHARED CARE AGREEMENT LETTER

Name of GP: ……..… Address: ……..
…….
…….
..……

Dear GP

Re: Patient's Name: ……..……....

Date of Birth: ……..…….

Hospital Number: ……..…….

Indication for use of **Somatropin** (Recombinant Human Growth Hormone)…….……

Route: *Subcutaneous injection*

Dose: ……. *micrograms* per ……..

Enclosed is a copy of the shared care guidelines for Somatropin to be retained in the patient's notes.

Should you agree to shared care, we will send a letter containing the details of the patient's treatment plan, the dose to be prescribed and all relevant blood results.

Please sign below and return this letter to the Hospital Specialist if you agree to the shared care arrangements for this patient.

Many thanks

Hospital Specialist

Signature: ……...

Name: ……..……....

Date: …….....

GP

Signature: ……...

Name: ..……...

Date: ..……..…..……..

If you are not taking on shared care for this patient please state the reason why and return this letter to the Hospital Specialist.

……
……
……

Information for Patients prescribed Somatropin (Growth Hormone)

You have been prescribed **somatropin** by a specialist for the treatment of growth hormone deficiency.

What is Growth Hormone?

Growth hormone is normally produced by the pituitary gland, which lies at the base of the brain. Naturally occurring human growth hormone is also called somatotrophin. It helps to control the body's use of proteins, carbohydrates and lipids. Growth hormone is also involved in the growing process in children, as it has an effect on the growth of bones.

Growth hormone deficiency is the term used when the amount of growth hormone produced is much lower than usual. In adults, growth hormone deficiency can happen as a result of damage to the pituitary gland or to the part of the brain called the hypothalamus, which is closely linked to the pituitary. Such damage can be caused by a tumour in the area or by the treatment the person had for the tumour (surgery or radiotherapy). Growth hormone deficiency can also happen if there has been a problem with the blood supply to the pituitary or hypothalamus.

What should I know about my medication?

- Read all of the information in the leaflet supplied with your medication before using it
- Do not use if you are allergic to somatropin, to phenol or any other ingredient listed in the product ingredients
- If any of the side effects (see list below) become troublesome or you notice any side effects not listed in the information leaflet, please tell your doctor or pharmacist
- Tell your doctor or pharmacist if you have any other medical conditions and if you are taking other medicines or have recently taken any. This includes medicines obtained without a prescription
- Inject your daily dose into the skin every evening before bedtime
- Tell your doctor if you inject too much somatropin
- If you forget a dose, take the next dose as usual at the normal time. Do not take a double dose to make up for a forgotten dose. Keep a record of any missed doses and inform your consultant or GP at your next appointment
- Do not stop using somatropin without discussing with your doctor first

What are the main side effects in adults?

Very common: (affects more than 1 user in 10)

- Swollen hands and feet due to fluid retention

Common: (affects 1 to 10 users in 100)

- Headache
- Feeling of skin crawling
- Numbness or pain mainly in fingers
- Joint pain and stiffness, muscle pain

Uncommon: (affects 1 to 10 users in 1,000)

- Type 2 diabetes
- Carpel tunnel syndrome – tingling and pain in fingers and hands
- Itching (can be intense) and pain in area of injection
- Muscle stiffness

Recommended Patient Help Groups:

The Pituitary Foundation
PO Box 1944, Bristol BS99 2UB
Tel/Fax 08707743355
Email: helpline@pituatry.org.uk