# SHAREd CARE GUIDELINE FOR USE OF HUMAN GROWTH HORMONE
(SOMATROPIN) IN ADULTS

## Introduction

**Indication**

Growth hormone (GH) has been the subject of a NICE review (August 2003) and this Shared Care Protocol has been written in line with the recommendations of NICE.

GH is indicated when all the following criteria are satisfied

- Severe GH deficiency (defined as peak GH < 9 mU/l during stimulation test)
- Deficiency of other pituitary hormones on appropriate treatment
- Low quality of life (defined as score > 10/25 on ‘Quality of life assessment of growth hormone deficiency in adults’ (AGHDA) questionnaire)

The exception to this rule is that patients who were already on GH treatment prior to the publication of the NICE guidance may continue on treatment if they and their endocrinologist agree.

## Dosage & duration

GH is given by **subcutaneous injection** at an individually titrated dose, usually in the range of 200 - 800 micrograms per day, usually at bedtime. It is initially given as a 9 month trial and then on a long-term basis if the trial is successful. The first 3 months of the trial are to allow dose titration.

## Hospital specialist responsibilities

**Initial prescribing**

- The first 9-month of GH treatment will be supplied by the Endocrine Team. Patient education will also be delivered by the Endocrine Team.
- Continue to prescribe until GP has agreed to share care and confirmed date for transfer of care.

**Monitoring undertaken & frequency**

At **baseline** and at **9 months** the following will be assessed:

- Serum insulin-like growth factor-I (IGF-I)
- AGHDA questionnaire
- Body composition by Bioelectrical impedance
- TFT, FBC, HbA1c, lipid profile
- Bone mineral Density by DEXA when appropriate

Two weeks after treatment has started the IGF-I concentration will be measured and the GH dose adjusted to obtain an IGF-I concentration in the upper-half of an age-adjusted reference range. IGF-I will be measured two weeks after each change of GH dose.

Where possible patients will be included in international post-marketing studies, such as Pfizer’s KIMS project (for Genotropin), designed to monitor for low frequency side-effects.
## Frequency of hospital review

Patients will be seen as follows:

- **At commencement of GH**
  - Endocrine Specialist Nurse to teach patient how to use GH.

- **Two weeks after GH initiation or each dose change**
  - Endocrine Specialist Nurse to check IGF-I level, obtain results and communicate need for dose change to patient and GP.

- **3 months**
  - Consultant review to ensure dose titration achieved and treatment well-tolerated.

- **9 months**
  - Consultant review of the subjective and objective effects of the GH trial. GH will be continued if the patient wishes to continue and the NICE criteria (fall in AGHDA score of 7 or more points from baseline) are met.

- **Annual review**
  - Consultant and Endocrine Specialist Nurse review. More frequent review may be required depending upon the clinical context.

## Contact details - specialist, Clinical nurse specialist

Dr Richard Jenkins (Consultant Endocrinologist), Dr Dinesh Nagi (Consultant Endocrinologist) and Sister Julie Andrew (Endocrine Specialist Nurse) are all available through the Edna Coates Diabetes and Endocrine Unit, Pinderfields General Hospital, Aberford Road, Wakefield, WF1 4DG. Telephone 01924-213911.

## GP responsibilities

Prescribing (when patient stable)

The GP will be responsible for prescribing GH after the initial 9-month trial period.

### Monitoring required & frequency

No GH specific monitoring is required by the GP.

### Interpretation of results & when to refer back to specialist

Patients on GH will not be discharged from the Endocrine clinic. If a patient presents to the GP with a problem that may be GH-related then review by the Endocrine team should be arranged.

## Product information

### Common side effects *

Side-effects are uncommon when GH is started at a low dose and then slowly titrated to the effective dose. However, the commonest side-effects are arthralgia, fluid retention and headache. If side-effects are suspected then the endocrine team should be contacted and dose adjustment considered. Glucose levels may rise. Please see the BNF or Data Sheet for a full list of side-effects.

### Important drug interactions *

There are no important interactions with other drugs.
Licensed status – POM
GH is licensed for treatment of adult GH deficiency. It is also licensed for use in a number of conditions in childhood but these are outwith the scope of this document.

Preparation & storage
There are 6 brands of GH in the UK; the following are used locally.

**Genotropin**: Two preparations are available – either a Genotropin pen with two-compartment cartridges containing powder for reconstitution and diluent or a MiniQuick pre-loaded syringe supplied with needles. The cartridges and pen should be stored in a fridge 2-8 °C.

**Norditropin**: Available as a SimpleXx injection using the NordiPen device. The cartridges and pen should be stored in a fridge at 4 °C.

**NutropinAq**: 2ml x 10mg cartridges. The cartridges and pen should be stored in a fridge 2-8°C.

Availability
**Growth hormone** is available through community pharmacists or through homecare delivery services. The hospital will register patients with a homecare service if this is the preferred method of delivery by the patient.

**Pens** available free of charge from hospital Endocrine department.

**Replacement pens, needles, sharps bins, cool bags** etc available free of charge to patients by contacting appropriate company Helpline:
- Genotropin Helpline 0800 521 249.
- NordiCare for Norditropin – 0800 028 5052
- HomeZone via Healthcare at Home for NutropinAq – 0800 096 4283

Basic NHS cost per month
For daily dose of 0.2 - 1.0mg subcutaneously approx. £120 - £660 per month.

Communication
**Hospital specialist to GP**
A letter will be sent to the GP seeking agreement to a shared care arrangement for each new patient, whenever treatment is changed, after each clinic review and whenever any other significant event occurs.

**Information given to patient**
Patients are given comprehensive one-to-one education about the use and self-administration of GH by the Endocrine Specialist Nurse. This is supported by written information, educational videos and details of relevant contact numbers.

**GP to Hospital specialist**
- The GP will confirm willingness to accept prescribing responsibility as soon as practicable & confirm date for transfer of care.
- The GP will inform the Endocrine team of any significant clinical changes that the patient brings to their attention or relevant changes in medication.

Authorship & date prepared
Prepared by Dr Richard Jenkins and Sister Julie Andrew.
Approved by NKWAPC June 2005

Review date
June 2007

This information is not inclusive of all prescribing information and potential adverse effects. Please refer to the SPC (www.emc.medicines.org.uk) or BNF for further prescribing information.