South West Yorkshire Area Prescribing Committee

Somatropin (Growth Hormone) in adults

Introduction	
General statements	• The patient will receive supplies of the drug from the hospital until the transfer of shared care is agreed between consultant and GP. • Injection device and ancillaries will be provided by the relevant Homecare company and Hospital specialist. • Patients will be given contact information for replacement of ancillaries from their Homecare company. • The GP must reply in writing to the request for shared care within two weeks if unwilling to participate. • The responsibility for prescribing and monitoring must be documented clearly in the patient's hospital and GP notes. • Shared care should only be considered when the patient's clinical condition is stable or predictable.
Indication	Growth hormone (GH) has been the subject of a NICE review (TA 64 August 2003). This Shared Care Protocol has been developed and reviewed in line with the recommendations of NICE. GH in adults 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 are appropriately treated • 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.
Individual's Responsibilities	
Hospital specialist's responsibilities	• The first 9-month of GH treatment will be supplied by the Endocrine Team. • Patient device training education will also be delivered by the Endocrine Team. • Monitoring as described below
General Practitioner's responsibilities	• The GP will be responsible for prescribing GH after the initial 9 month trial period. (The relevant home care company will request prescriptions directly from the GP) • No GH specific monitoring is required by the GP • 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.
Monitoring required	At **baseline** and at **9 months** the following will be assessed: • Serum insulin-like growth factor-I (IGF-I) • AGHDA questionnaire • 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. **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 for information only. • 3 months. Endocrine Nurse 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.
When and how to discontinue treatment	Treatment should be discontinued by hospital specialist only
Information given to the 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.
Contact details	Documented in letter from Hospital Specialist to GP

Product Information

The information in this Shared Care Guideline should be used in conjunction with the latest edition of the BNF and Summary of Product Characteristics

Dosage	GH is given by **subcutaneous injection** at an individually titrated dose, usually in the range of **200micrograms – 1mg 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.
Serious adverse 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. Refer to the current BNF and www.medicines.org.uk/emc/ for complete and up to date information.
Precautions and contra-indications	**Evidence of tumour activity, not to be used after renal transplantation.**
Clinically relevant drug interactions and their management	Increased doses may be needed when given with oestrogens. Refer to the current BNF and www.medicines.org.uk/emc/ for complete and up to date information.