Somatropin (Recombinant Human Growth Hormone) Treatment for Adults Effective Shared Care Agreement

Section 1: Shared Care arrangements and responsibilities

Section 1.1 Agreement to transfer of prescribing of Somatropin to GP

Patient details

Name: _____

Address: _____

Date of Birth: _____

NHS number: _____

Contact details
Specialist:
Address:

Email:

Contact number:

GP

Address:

Email:

Contact number:

Patient

Name:

Contact number:

Agreement to shared care, to be signed by GP and Specialist before prescribing is transferred to GP

Specialist Signature: _____

Date: _____

GP Signature: _____

Date: _____

Patient Signature: _____

Date: _____

Section 1.2: Shared Care responsibilities

This shared care agreement outlines suggested ways in which the prescribing responsibilities can be shared between the specialist and GP. GPs are invited to participate. If the GP feels that undertaking the roles outlined in the shared care agreement is outside their area of expertise or have clinical concerns about the safe management of the drug in primary care, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient's health remains with the specialist. If a specialist asks the GP to prescribe, the GP should reply to this request as soon as practicable.
Sharing of care assumes communication between specialist, GP and patient.

If a specialist asks the GP to prescribe, the GP should reply to this request within 2 weeks

The prescriber of the medication legally assumes clinical responsibility for the drug and the consequences of its use.

Responsibilities of the specialist initiating treatment

- Discuss with the patient options for treatment and the suitability of somatropin
- Discuss the potential benefits and side effects of treatment with the patient
- Monitor clinical and laboratory values appropriate to the underlying diagnosis.
- Undertake clinical assessment of general health, assessment of quality of life using QoL-AGHDA
- Ensure patient fulfills NICE criteria for treatment.
- Complete the NICE notification template, available from Growth Hormone NICE template
- Initiate somatropin treatment
- Ask the GP whether he or she is willing to participate in shared care, and agree with the GP as to who will discuss the shared care arrangement with the patient.
- Titrate somatropin to an effective dose. If both GP and Specialist feel it is appropriate, shared care may be initiated before the patient is stabilised on the effective dose, as long as the dose is stable until the next Specialist appointment. .
- Ensure agreed signed shared care form has been received back from GP to indicate that the GP is in agreement with prescribing and monitoring.
- Ensure this has been discussed with patient, and that patient has signed SCA form
- Regular follow-up of patient (at least annually)
- Communicate promptly with the GP when treatment is changed
- Advise GP on dosage adjustment and when and how to stop treatment
- Have a mechanism in place to receive rapid referral of a patient from the GP in the event of deteriorating clinical condition and ensure that clear backup arrangements exist for GPs to obtain advice and support
- Report adverse events to the MHRA (via Yellow Card)

Responsibilities of the General Practitioner

- Prescribe somatropin as recommended.
- Arrange and record on-going monitoring as agreed with specialist:
- Ensure no drug interactions with other medicines
- Continued prescribing is appropriate for patients attending regular review
- Report adverse events to the MHRA (via Yellow Card)

Responsibilities of the patient

- To administer the prescribed medication regularly unless advised by GP or specialist

- To attend scheduled appointments with Specialist and GP and for monitoring as detailed above
- Report any adverse effects to the Specialist or GP.
- Share any concerns in relation to treatment.
- Report to the Specialist or GP if they do not have a clear understanding of the treatment

Section 2: General Information on Somatropin

Licensed Indication

Replacement therapy in adults with pronounced growth hormone deficiency.

NICE criteria[1]

Recombinant human growth hormone (somatropin) treatment 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.

The QoL status of people who are given GH treatment should be re-assessed 9 months after the initiation of therapy (an initial 3-month period of GH dose titration, followed by a 6-month therapeutic trial period). GH treatment should be discontinued for those people who demonstrate a QoL improvement of less than 7 points in QoL-AGHDA score.

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 based on all the criteria above.

Dosage and administration

The recommended starting dose is 0.15-0.30mg/day. A lower starting dose may be necessary in older and obese patients.

This dose should be gradually increased according to individual patient requirements based on the clinical response and serum IGF-I concentrations. Total daily dose usually does not exceed 1mg.

Growth hormone replacement is administered as a daily subcutaneous injection at bedtime.

Usually, the drug is supplied in disposable pens containing two cartridges (of powder and diluent), which are mixed inside the pen pre-injection. Alternative injections are available as single dose premixed injection packs.

Preparations available: Genotropin (Pharmacia); Humatrope (Lilly); Norditropin (Novo Nordisk); Saizen (Merck Serono), NutropinAq (Ipsen), Omnitrope (Sandoz)

Contraindications

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

Any evidence of tumour activity. Anti-tumour therapy must be completed prior to starting therapy.

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.

Side effects

Sodium retention (oedema, carpal tunnel syndrome) is only common with higher doses and can usually be relieved by a reduction in dose.

Arthralgia and myalgia can occur but are also dose-dependent and usually transient.

Intra-cranial hypertension is rare, but any severe persistent headache should be reported to specialist initiating treatment and the patient will be reviewed early.

Hypothyroidism is a complication, which is not relevant in most patients, who are already receiving thyroxine.

There has been concern that growth hormone would accelerate growth of neoplasm's. There is no evidence that it does so for pituitary tumours

Drug Interactions[2]

Concomitant treatment with glucocorticoids may inhibit the growth-promoting effects of somatropin containing products. Therefore, patients treated with glucocorticoids should have their growth monitored carefully to assess the potential impact of glucocorticoid treatment on growth.

Somatropin administration may increase the clearance of compounds known to be metabolised by cytochrome P450 isoenzymes. The clearance of compounds metabolised by cytochrome P 450 3A4 (e.g. sex steroids, corticosteroids, anticonvulsants and ciclosporin) may be especially increased resulting in lower plasma levels of these compounds.

[1] NICE TA64 Human growth hormone (somatropin) in adults with growth hormone deficiency August 2003
[2] BNF 70 September 2015-March 2016