HERPC

Hull & East Riding Prescribing Committee

Prescribing Framework for Somatropin for Adult Growth Hormone Deficiency

Patient's Name:…….. NHS Number: ……

Patient's Address:……(Use addressograph sticker)

GP's Name:……..

Communication

We agree to treat this patient within this Prescribing Framework

Specialist Prescriber's Name…… Prof Reg. No. ……

Specialist Prescriber's Signature…… Date:…….

Where prescriber is <u>not</u> a consultant:

Consultant's Name: …… GMC No ……..

Consultant's Signature ……... ……. Date:…….

GP's Signature:…… Date:……..

GP's Name (if different from listed above)……..

The front page of this form should be completed by the specialist and the form sent to the patient's general practitioner.
The patient's GP should sign and send back to specialist, to confirm agreement to enter into shared care arrangement. If the General Practitioner is **<u>unwilling</u>** to accept prescribing responsibility for the above patient the specialist should be informed within two weeks of receipt of this framework and specialist's letter.

1. Background

Patients with severe adult growth hormone deficiency have an abnormal body composition, lipid profile, impaired physical performance, reduced bone mineral density, and impaired quality of life. Studies have shown an increase in cardiovascular and cerebrovascular mortality.

The diagnosis of growth hormone deficiency is based on clinical features, confirmed by two provocative tests of dynamic growth hormone reserve (only one provocative test is needed if there are additional pituitary hormone deficiencies), which are usually an insulin stress test and a glucagon stimulation test with a peak growth hormone response of <3ng/ml (<9mU/L) to the provocative stress. In addition, measures of IGF-1 levels, HbA1c, and DEXA scanning for bone mineral density are performed. All patients have a quality of life assessment using the 'Quality of life assessment of growth hormone deficiency in adults' (QoL-AGHDA) questionnaire.

The guidelines should be read in conjunction with the general guidance on prescribing matters given in EL (91) 127 "Responsibility for prescribing between hospitals and GPs".

2. Indication

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 (as listed in NICE TA64).

- They have severe GH deficiency, defined as a peak GH response of less than <3ng/ml (<9mU/L) 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 ADGHA-QoL questionnaire.
- They are already receiving treatment for any other pituitary hormone deficiencies as required.

3. Dose/formulation

The initiation of treatment is normally at a low dose, starting at 0.1µg/day (0.3IU/day) which is delivered by subcutaneous self injection on a daily basis. Somatropin dosage is re-evaluated every 4-6 weeks for the next 3 months. The success of the treatment can be monitored by normalisation of the IGF-1 levels and treatment is tailored to this by the supervising Endocrinologist. Patients may sometime need titration for more than 3 months to reach adequate maintenance dose.

The patient will be given a choice of various delivery devices used to administer and allowed to select the device based on cost-effectiveness and suitability for the patient.

4. Duration of treatment

The QoL status of people who are given GH treatment should be re-assessed, usually 9 months after the initiation of therapy (an initial titration period usually of 3-months, 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.

Treatment will be reviewed at regular 6 to 12 monthly intervals by the Consultant Endocrinologist in conjunction with the General Practitioner. Therapy may be prescribed 'life-long' for those who demonstrate a significant QoL improvement.

5. Contraindications

Somatropin should be discontinued in pregnancy. Although it has not been shown to be teratogenic there are theoretical risks to the foetus.
Active malignancy – Somatropin should be discontinued after discussing with specialists.

6. Adverse effects

In a multi-centre European double blind placebo controlled growth hormone study, of 115 patients who received growth hormone in the first 6 months of the study 37% developed peripheral oedema, 19% arthralgia, 16% myalgia, 8% paraesthesia and 2% carpal tunnel syndrome. These side effects are usually mild and self-limiting and often decrease as therapy continues. However, initial dose reduction may be occasionally required.

In patients with diabetes, somatropin therapy may reduce insulin resistance requiring a modification of their oral hypoglycaemic or insulin regimen.

See www.bnf.org or www.medicines.org.uk for further details.

7. Interactions

- Corticosteroids – may inhibit growth-promoting effects of somatropin
- Oral oestrogen (as HRT) – increased doses of somatropin may be needed

See www.bnf.org or www.medicines.org.uk for further details.

8. Monitoring

Initially pre therapy: assessment of height, weight, BMI, BP and pulse and biochemically a full pituitary hormone profile, biochemical profile, full blood count, fasting lipid profile including HDL, and HbA1c.

Titration: Weight, body mass index, blood pressure and IGF-1 at each appointment, every four weeks from dose adjustment or last visit if no dose changes. There will be three clinic appointments and if required titration through telephone by Endocrine Specialist Nurse until therapy optimised.

Long term: Specialist to liaise with GP at regular intervals, to review treatment benefits.
Review patient at 6-12 monthly intervals for clinical examination, and biochemical assessment.

9. Information to patient

Patients will be educated as to the condition of which they suffer and advised about symptoms and side effects of growth hormone therapy. They have access in office hours to the Endocrinology Specialist Nurse for ongoing queries and support.

Patient support information is available from the Pituitary Foundation (www.pituitary.org) and will be given to the patient if they wish to receive it.

10. Responsibilities of clinicians involved

Stage of Treatment	**Hospital Specialist/Endocrinology Specialist Nurse**	**General Practitioner**
Initiation	Perform tests required to diagnose growth hormone deficiency. Prescribe and arrange supply of somatropin for the first 6 months. Review the patient at monthly intervals for the first three months for titration and three monthly thereafter for 6 months as therapeutic trial period. Perform QoL assessment after 6 months of therapeutic trial period and decide regarding continuation GH therapy. Provide patient with information on diagnosis and treatment. Provide education to patient/carer on the delivery device, administration and storage.	Phlebotomy may be needed for blood tests to optimise efficacy of tests or for patient convenience.
Maintenance	Liaise with GP at regular intervals, to review treatment benefits. Review patient at 6-12 monthly intervals for clinical examination, and biochemical assessment.	Continue to prescribe somatropin, as advised by consultant. Phlebotomy may be needed for blood tests to optimise efficacy of tests or for patient convenience. Liaise with consultant at regular intervals, to review treatment benefits.

Contact Details:

During Office hours: Consultant Endocrinologist on 01482 675340/675341

Endocrinology Specialist Nurse on 01482 675360

Out of hours: On-call Endocrinology Consultant or Registrar via HRI Switchboard (01482 875875).

APPROVAL PROCESS

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