West Devon Shared Care Guideline ~ Somatropin for the treatment of growth hormone deficiency in adults

April 2013

Specialist: Please complete the Shared Care letter sending a request to GP (see bottom of the page)
GP: Please indicate whether you wish to share patient's care by completing letter and return to specialist

Aim of Treatment

Somatropin (recombinant human growth hormone (GH)) has been available for many years and is used safely in children with growth hormone deficiency, renal failure, and Turner's syndrome. Somatropin has also been licensed for use in adults since 1995:

1. Patients with hypopituitarism (most commonly due to pituitary tumours) receive replacement with hydrocortisone, levothyroxine, sex steroids and sometimes DDAVP. However, despite careful titration of these therapies, hypopituitary patients have residual problems, including lethargy, reduced muscle mass, central obesity, and an increased risk of cardiovascular mortality.
2. There is evidence that growth hormone replacement produces beneficial effects on muscle mass and strength, body fat distribution, blood lipid levels, insulin sensitivity, bone mineral density, and cardiac output. Most importantly, some patients experience a dramatic improvement in well-being and quality of life. This response is hard to predict and varies markedly between patients.
3. In 2003 NICE recommended GH therapy for the treatment of adults with GH deficiency only if they fulfil all three of the following criteria:
   a. They have severe GH deficiency, defined as a peak GH response of 9mU/litre or less during an insulin tolerance test or a cross validated GH threshold in an equivalent test.
   b. They have a perceived impairment of quality of life (QoL), as demonstrated by a reported score of at least 11 in the disease specific 'QoL assessment of GH deficiency in adults questionnaire'.
   c. They are already receiving treatment for any other pituitary hormone deficiencies as required.
4. NICE state the QoL status of people who are given GH treatment should be reassessed 9 months after initiation of therapy.

Specialist responsibilities

1. To assess the patient and establish then need for growth hormone with provision of appropriate information on growth hormone deficiency and its treatment
2. To initiate treatment and titrate the dose including review of the patient at monthly intervals. **Prescribe somatropin by brand.**
3. To monitor clinical and laboratory values appropriate to the underlying diagnosis, including IGF-1. Clinical assessment of general health, assessment of quality of life by disease specific questionnaire
4. Adjustment of dosage
5. To arrange hospital supply of growth hormone and injection aids until Shared care is agreed with the GP
6. To teach the patient self-injection technique
7. To review the patient every 6-12 months
8. To send a letter to the GP requesting Shared care for a particular patient. Specialist to specify brand to be prescribed.
9. To evaluate any reported adverse event reported by the GP or patient

General practitioner responsibilities

If GP has agreed to share care:

1. To contact the referring consultant without delay if they do not wish to enter into a Shared care agreement
2. To assess the continued well-being of the patient including adverse drug reaction and drug interaction monitoring and report to the referring consultant where appropriate
3. **To prescribe somatropin by brand** including dosage adjustment according to specialist recommendation
4. To contact the referring consultant as appropriate

Back-up advice and support

Endocrinology Consultants:

- Taz Babiker
- Patrick Chong
- Nidhi Choudhary
- Diana Clayton
- Ioannis Dimitropoulos
- Kate Evans
- Daniel Flanagan
- Sherif Ghieth

The individual consultants may be contacted via the endocrinology secretary: 01752 439812

Endocrinology Nurse:

The endocrinology nurse team may be contacted via the following email address:
plh-tr.adultendocrineprescriptionrequests@nhs.net

Derriford Medicines Information:

01752 439976

Medicines Optimisation Teams:

- NHS Devon Integrated Care Board: 01752 398800
- NHS Cornwall and Isles of Scilly Integrated Care Board: 01726 627953

Supporting Information

Refer to the SPCs and BNF for further information.

Preparations

All preparations are chemically equivalent. Refer to the BNF for available brands and formulations.

Somatropin is a biosimilar medicine; it is a biological medicine that is highly similar and clinically equivalent (in terms of quality, safety, and efficacy) to an existing biological medicine however they cannot be considered generic equivalents of the originator biological medicine. Because they are not identical, **biological medicines must be prescribed by brand**.

The decision which brand to prescribe rests with the specialist in consultation with the patient. Automatic substitution of brands at the point of dispensing is not appropriate for biological medicines.

Dose

Growth Hormone replacement is administered as a daily subcutaneous injection at bedtime. The injection site should be varied to prevent lipoatrophy.

The starting dose is usually 0.15-0.3mg daily adjusted until a satisfactory clinical and biochemical response (based on maintaining circulating levels of Insulin-like Growth Factor (IGF-1) within the appropriate physiological age related range. The recommended final GH dose seldom exceeds 1.0mg/day.

Contraindications

- Hypersensitivity to somatropin or any excipients
- Active malignant tumours
- Benign intracranial hypertension
- Renal transplantation
- Acute critical illness suffering complications following open heart surgery, abdominal surgery, multiple accidental trauma, acute respiratory failure or similar conditions
- Pregnancy – somatropin containing products are not recommended during pregnancy and in woman of childbearing potential not using contraception.

Cautions

- Diabetes mellitus
- Papilloedema
- Relative deficiencies of other pituitary hormones
- History of malignant disease
- Disorders of epiphysis of the hip
- Resolved intracranial hypertension
- Silver-Russell syndrome
- Breast feeding

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 and the patient will be reviewed early
- Hypothyroidism is a complication which is not relevant in most patients, who are already receiving levothyroxine
- There has been concern that growth hormone would accelerate growth of neoplasms. There is no evidence that it does so for pituitary tumours

Interactions

The following drugs have a potential interaction with growth hormone, and caution must be used when prescribing concurrently:

- Corticosteroids – growth promoting effect may be inhibited
- Oestrogens (when used as oral replacement therapy) – increased doses of somatropin may be required

Shared Care Agreement Letter – Consultant Request

To: Dr……

Practice Address……..

…….

…….

Patient Name:	
NHS Number:	
Date of birth:	
Address:	

Diagnosed condition: ……....

I recommend treatment with the following drug: ……

At the following dosage: ……....

Important: Somatropin must be prescribed by brand.

I request your agreement to sharing the care of this patient according to the Western Locality Shared Care Information guidelines for this drug. The patient has been initiated on treatment and stabilised in accordance with the appropriate Shared Care Information.

Principles of shared care:

GPs are invited to participate, but **if the GP is not confident to undertake these roles then they are under no obligation to do so.** If so, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If asked to prescribe this drug the GP should reply to this request as soon as practical. Sharing of care assumes communication between the specialist, GP and patient. The intention to share care should be explained to the patient and accepted by them.

Remember: the doctor who prescribes the medication has the clinical and legal responsibility for the drug and the consequences of its use.

Signed:			Date:
Consultant name:			
Telephone number:		Fax number	
Email address			

GP please sign below and return promptly. Remember to keep a copy of this letter for the patient's records. If this letter is not returned shared care for this patient will not commence.

GP Response

I agree / do not agree* to share the care of this patient in accordance with the Shared Care Guideline.

Signed: …….. Date: …….

GP name: ……. *Delete as appropriate.