The Shrewsbury and Telford Hospital NHS
NHS Trust

NHS
Telford and Wrekin
Clinical Commissioning Group

# Somatropin (Recombinant Human Growth Hormone) Treatment for Children 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

**Initiation**

- Confirm diagnosis for one of the following:
  - Growth Hormone deficiency
  - Small for Gestational Age (SGA) with subsequent growth failure at 4 years of age or later.
  - Short Stature Homeobox gene (SHOX) Deficiency
  - Turner Syndrome (TS)
  - Chronic Renal Insufficiency (CRI)
  - Prader-Wili Syndrome(PWS)
- Initiate growth hormone treatment and provide prescriptions until care is transferred to GP, usually after 2-3 months.
- Provide patient and/or their carer with written and verbal information and discuss potential benefits and side-effects of treatment before it is started.
- Select appropriate presentation.
- Train patient in administration and storage.
- Ask the GP whether he or she is willing to participate in shared care and explain the intention to share care with the patient and carer.
- Provide the GP with the following information: diagnosis results of endocrine test, somatropin brand, device and dose to be prescribed, quantity supplied by hospital and date the next prescription is required.
- Ensure clear backup arrangements exist for GP for advice and support.

**Follow-up and Monitoring**

- Monitor the response to treatment every 3-6 months. See supporting information for monitoring requirements.
- Write to the GP every 3-6 months advising of results of assessments/tests, response to treatment and any dose adjustment required.
- Check for concordance with treatment.
- Check for side effects and report suspected serious adverse drug reactions, and all suspected adverse drug reactions for black triangle drugs, to the MHRA using the yellow card scheme.
- Stop growth hormone treatment when indicated and to write to the GP to confirm this.
- Arrange transition to adult service when appropriate.

## Responsibilities of the General Practitioner

- Reply to the request for shared care as soon as practical.
- Prescribe growth hormone treatment by BRAND name as recommended by the specialist.
- Make dosage adjustments if requested to by the specialist.
- Report any adverse effects thought to be related to the somatropin to the specialist. See supporting information for further details.
- Report suspected serious adverse drug reactions, and all suspected adverse drug reactions for black triangle drugs, to the MHRA using the yellow card scheme.
- Check for interactions with other medicines and report to the specialist significant changes or additions to a patient's medication.
- Treat respiratory infections promptly and aggressively.
- Refer patients presenting with limp to the specialist for further investigations.
- Investigate possibility of pancreatitis in patients presenting with severe abdominal pain.
- Investigate possibility of otitis media if patient complains of ear pain.
- Re-refer or seek specialist advice if concerned about the patient's condition in between regular reviews.
- Stop prescribing growth hormone if requested to do so by the specialist.

## Responsibilities of the patient

- With the specialist, select the most appropriate somatropin device.
- Administer somatropin daily.
- Store the medication according to the manufacturer's recommendations and out of reach of children.
- Request repeat prescriptions from the GP at least a week before required and present ASAP to usual community pharmacy for dispensing to ensure a sufficient quantity of medicine is available for use at all times.
- Seek medical advice from GP if any side effects are experienced.
- Attend appointments with the specialist or GP, including scheduled blood tests.
- Vary the injection site to prevent lipoatrophy.
- Seek prompt medical advice if patient experiences signs of upper airway obstruction (snoring) or respiratory infections.
- Seek prompt medical advice if patient develops a limp.
- Seek prompt medical advice if patient develops a headache, especially if early morning, and starting within a few days/weeks of starting GH.
- Seek prompt medical advice if patient develops severe abdominal pain.
- Seek prompt medical advice if patient develops abnormal curvature of spine.
- Seek prompt medical advice if patient develops ear pain.
- In Prader-Wili Syndrome monitor weight as instructed by the specialist and seek medical advice if significant weight gain.

# Section 2: General Information on somatropin

## Licensed Indication

- Proven growth hormone deficiency. Diagnosis is made by documentation of slow growth, clinical features, delayed bone maturation and appropriate specialist investigations.

- Turner syndrome. Ideally this is diagnosed early (even at birth) and GH treatment initiated at 2-3 years of age to maximise final height.

- Chronic renal failure. Before GH treatment is given the child's nutrition and metabolism should be optimised and steroid dose as low as possible.

- Prader-Willi syndrome

- Small for Gestational Age (SGA) with subsequent growth failure at 4 years of age or later.

- Short Stature Homeobox gene (SHOX) Deficiency

**Not all brands of somatropin are licensed for every indication; therefore the individual Summary of Product Characteristics should be consulted.**

This shared care agreement supports the implementation of NICE Technology Appraisal TA188 Human growth hormone (somatropin) for the treatment of growth failure in children: guidance, July 2010

## Dosage and administration

The injection should be given subcutaneously and the site varied to prevent lipoatrophy.

- GH deficiency in children: 25–35 micrograms/kg daily or 0.7– 1 mg/$m^2$ daily.
- Turner syndrome: 45–50 micrograms/kg daily or 1.4 mg/$m^2$ daily. (Norditropin 45-67 µg/kg/day or 1.3-2.0 mg/$m^2$/day)
- Chronic renal insufficiency (renal function decreased to less than 50%): 45–50 micrograms/kg daily or 1.4 mg/m2 daily (higher doses may be needed) adjusted if necessary after 6 months.
- Prader-Willi syndrome: in children with growth velocity > 1 cm/year, in combination with energy-restricted diet, 35 micrograms/kg daily or 1 mg/$m^2$ daily; max. 2.7 mg daily**.** Growth disturbance in short children born small for gestational age whose growth has not caught up by 4 years or later, by subcutaneous injection, 35 micrograms/kg daily or 1 mg/$m^2$ daily
- SHOX deficiency in children, by subcutaneous injection, 45–50 micrograms/kg daily

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

## 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.

Within one year of renal transplant.

Severe respiratory impairment in patients with Prader-Willi syndrome.

Children with closed epiphyses.

## 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,

There has been concern that growth hormone would accelerate growth of neoplasms. There is no evidence that it does so for brain tumours

Children treated with somatropin have an increased risk of developing pancreatitis compared to adults treated with somatropin. Although rare, pancreatitis should be considered in somatropin-treated children who develop abdominal pain.

## Drug Interactions[1]

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 P450 3A4 (e.g. sex steroids, corticosteroids, anticonvulsants and ciclosporin) may be especially increased resulting in lower plasma levels of these compounds.

## Monitoring

Specialist should monitor all children receiving GH. Treatment should be re-evaluated and usually stopped if there is a poor response (less than 50% increase in growth velocity from baseline in the first year of therapy).

Specialist will monitor pituitary hormones. This includes monitoring thyroid function annually and after any dose change.

Response should be evaluated using standard growth charts. Therapy is normally stopped when final height is approached (height increment <2cm / year).

Monitoring compliance of injections should be considered when ‘response to treatment’ is poor.

In Prader-Willi syndrome it is important to monitor changes in body composition as part of evaluation.
Specialist should monitor until growth is complete, when treatment will be stopped. Decisions must then be made about reassessing for GH deficiency (GH treatment in adulthood may be appropriate) and transfer to the adult services.

GH is an insulin antagonist; GH administration could therefore unmask latent diabetes and would be expected to increase the insulin requirement in patients with established type 1 diabetes.

The GP should be observant for the following:

- In case of severe or recurrent headache, visual problems, nausea and/or vomiting, a fundoscopy for papilloedema is recommended.
- Observe for signs of upper airway obstruction (snoring) and treat respiratory tract infections aggressively.
- Investigate possibility of pancreatitis in patients presenting with severe abdominal pain.
- Investigate possibility of otitis media if patient complains of ear pain.

[1] BNF 66 September 2013-March 2014.