

Shared care guidelines for paediatric use of daily and long-acting recombinant human growth hormone

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Background

The BSPED growth hormone therapy shared care guidelines were produced by the BSPED Clinical Committee in August 2015. These guidelines were updated by the **BSPED Growth Disorders Special Interest Group (SIG)** in December 2023.

Recombinant human GH (r-hGH) is available as a daily (somatropin) or as long-acting growth hormone (LAGH) preparations. Currently somatrogen is the only LAGH preparation available but other LAGH preparations are likely to be licenced.

There are separate BSPED guidance/clinical standards available for the use of r-hGH:

- Standards for GH treatment for GHD
<https://www.bsped.org.uk/media/iczlv32f/clinical-standards-for-gh-treatment-of-ghd-in-childhood-and-adolescence-v1.pdf>
- Standards for GH treatment for other growth disorders excluding GHD
<https://www.bsped.org.uk/media/kfnh1ung/clinical-standards-for-gh-treatment-of-growth-disorders-excluding-ghd-19122023.pdf>
- Use of once-weekly long-acting growth hormone therapy in children with growth hormone deficiency
<https://www.bsped.org.uk/media/2xdjdr0q/lagh-guideline-24-04-2024.pdf>

Recombinant growth hormone (r-hGH) use in children and young people

Somatropin, also known as daily recombinant human growth hormone (r-hGH) is used to treat short stature secondary to several conditions and optimise body composition in Prader-Willi syndrome. **Somatropin** is recommended and approved by NICE^{1,2} as a treatment option for children with growth failure associated with the [1-6] conditions listed below. In 2019, Noonan syndrome was added to the approved UK licenced indications (but not yet NICE approved) for the somatropin preparation Norditropin [7].

LAGH (weekly injections) is now available in the UK and approved by NICE (2023) as an option for the treatment of growth hormone deficiency for children and young people aged three years and over^{3,4}.

Somatropin is licenced in the UK for use in children for the following conditions^{1,2}:

1. Growth hormone deficiency
2. Turner syndrome
3. Chronic renal failure
4. Prader-Willi syndrome
5. SHOX deficiency
6. Short stature secondary to being born small for gestational age
7. Noonan syndrome

Somatrogon is a LAGH (weekly) preparation licenced in the UK for use in children for: Growth hormone deficiency for children over the age of 3 years up until adult height has been reached.

General Guidance:

Shared care is the mechanism of sharing patient care between primary and secondary care providers. Sharing of care assumes good communication between the patient and all professionals in primary care (GP) & secondary care (hospital consultant, specialist nurses, pharmacist etc). The intention to share care with a GP should be explained to the patient and their carers by the specialist initiating treatment and an outline of responsibilities provided. The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use. If a GP is invited by a specialist to participate in a shared care arrangement and is not confident to undertake these roles, then he or she is under no obligation to do so but should discuss this with the specialist as soon as possible.

Shared Care Criteria

Treatment with r-hGH should always be initiated and monitored by a specialist (Consultant Paediatric Endocrinologist or Consultant Paediatrician with expertise in growth disorders). Prescribing should be in keeping with national guidelines for r-hGH usage in children, National Institute for Health and Care Excellence (NICE) and licenced indications for GH use in children¹⁻⁴.

General Guidelines for Shared Care Strategy:

1. Patients started on r-hGH therapy require specialist supervision and review in a growth/endocrine clinic 2-3 times a year.
2. r-hGH has a good safety record and is licensed for use in children fulfilling licensed criteria and / or stipulated by NICE¹⁻⁴.
3. Dose adjustments will be required intermittently and should be instigated by the supervising Consultant based on changes in height, weight, and IGF-1 levels.
4. Updates should be communicated to the GP by the supervising Consultant following every clinic visit.

Specialist / Consultant Responsibilities:

1. To undertake necessary testing to confirm a diagnosis that requires r-hGH treatment, as indicated above⁵⁻⁹.
2. To provide the GP with written information regarding the diagnosis and indication for r-hGH therapy along with dosage and preparation to be used.
3. To initiate therapy and supervise training and education of patients and families with r-hGH injections, liaise with GP about local arrangements necessary for instigation of therapy and identify any possible barriers to treatment.
4. Strict adherence to published NICE guidance for initial prescription of r-hGH and monitor ongoing r-hGH therapy^{1,2,4}.
5. The ongoing care by the specialist/ consultant will include the following:
 - To advise about dose changes, preparation changes, drug interactions, contra-indications, assess medicine adherence and inform GP of any changes
 - To monitor for side effects from r-hGH therapy
 - To monitor patient's growth and response to r-hGH, assess pubertal development,
 - To institute biochemical surveillance during r-hGH treatment
 - Assess ongoing or evolving endocrinopathy and general condition at 4-6 monthly intervals following instigation of therapy
 - Communicate with the GP after each clinic attendance including stating the current r-hGH dose
 - Blood results are communicated to patient, family and GP
 - To supervise the timing of cessation of treatment at final height and reassessment of the GH axis and where necessary other hormone status in those with a pituitary problem, according to Consensus guidelines.
 - Transition to adult endocrine care where necessary.

General Practitioner Responsibilities:

1. To prescribe r-hGH as advised by the supervising Consultant and, where local practice dictates, discuss with the local Prescribing Advisor; feedback to the consultant any concerns regarding r-hGH prescribing and/or shared care.
2. To monitor patient's overall health and well-being.
3. To report any adverse effects of therapy to the supervising Consultant or deputy.

Patient/Parent Responsibilities

1. To ensure they have clear understanding of the prescribed treatment.
2. To administer the r-hGH as directed by the supervising Consultant; attend clinic reviews as requested.
3. To share any concerns in relation to treatment with the supervising Consultant and/or GP.
4. To report any adverse effects to the supervising Consultant and/or GP whilst taking r-hGH.

Side effects of r-hGH²

- Benign intracranial hypertension
- Scoliosis
- Diabetes
- Slipped upper femoral epiphyses, osteonecrosis of femur
- Pancreatitis
- Hypothyroidism
- Arthralgia and myalgia
- Fluid retention, carpal tunnel syndrome
- Gynaecomastia
- Reactions at the site of injection

The following symptoms warrant assessment by medical services as a dose adjustment of r-hGH may be required:

- Persistent headache, visual problems, nausea, vomiting
- Persistent thirst, passing excessive urine
- Persistent abdominal pain
- Pain in hip or limp
- Persistent pain in joints
- Redness or inflammation at the site of injection

GP and Hospital Communication:

In case of concern regarding any aspect of a patient's care, please contact the supervising Consultant or deputy as soon as possible.

Name	Phone	Email Address
Consultant:		
Specialist Nurse:		
Other:		

References

1. Human growth hormone (somatropin) for the treatment of growth failure in children. National Institute for Health and Care Excellence. Technology appraisal guidance 26 May 2010. [Overview | Human growth hormone \(somatropin\) for the treatment of growth failure in children | Guidance | NICE](#)
2. Somatropin. British National Formulary for Children 2023. <https://bnfc.nice.org.uk/drugs/somatropin/>
3. NICE recommends a weekly injection for treating growth failure in children: <https://www.nice.org.uk/news/article/nice-recommends-a-weekly-injection-for-treating-growth-failure-in-children>

4. National Institute for Health and Care Excellence. Somatrogen for treating growth disturbance in children and young people aged 3 and over:
<https://www.nice.org.uk/guidance/ta863>
5. BSPED recommendations for the initial clinical assessment, investigation and genetic testing of children with growth failure and/or short stature:
<https://www.bsped.org.uk/media/1ylhw1qk/assessment-of-short-stature-final.pdf>
6. BSPED clinical standards for growth assessment and referral criteria for children with a suspected growth disorder:
<https://www.bsped.org.uk/media/oo1hsxet/clinical-standards-for-growth-assessment-and-referral-criteria-for-children-with-a-suspected-growth-disorder.pdf>
7. Standards for GH treatment for GHD <https://www.bsped.org.uk/media/iczlv32f/clinical-standards-for-gh-treatment-of-ghd-in-childhood-and-adolescence-v1.pdf>
8. Standards for GH treatment for other growth disorders excluding GHD
<https://www.bsped.org.uk/media/kfnh1unq/clinical-standards-for-gh-treatment-of-growth-disorders-excluding-ghd-19122023.pdf>
9. Use of once-weekly long-acting growth hormone therapy in children with growth hormone deficiency
<https://www.bsped.org.uk/media/2xdjdr0q/lagh-guideline-24-04-2024.pdf>