BSPED recommendations for the use of once-weekly long-acting growth hormone therapy in children with growth hormone deficiency

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Background

Long-acting growth hormone (LAGH) is now available in the UK and is recommended by NICE (2023) as an option for the treatment of growth hormone deficiency (GHD) for children and young people aged three years and over.

Currently two LAGH preparations are approved by NICE (somatrogon and somapacitan). This guidance focuses on these two preparations and will be updated when new LAGH preparations are accessible to patients in the UK. A "quick reference guide" is provided on pages 6-7, but we recommend reading the full guideline to understand the basis behind the recommendations in that table.

International consensus guidelines on the use of LAGH in children with GHD are also available and include somatrogon, somapacitan and lonapegsomatropin [1].

There are separate BSPED guidance/clinical standards available for:

- Shared care guidelines for growth hormone (GH) therapy https://www.bsped.org.uk/media/alxow2wv/gh-shared-care-guidelines-20240206.pdf
- 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/kfnh1unq/clinical-standards-for-gh-treatment-of-growth-disorders-excluding-ghd-19122023.pdf

In a global Phase III study [2], once weekly **somatrogon** at 0.66 mg/kg/week demonstrated non-inferiority to once daily somatropin in children with GHD with dose-dependent increases in height velocity and IGF-I concentrations between three doses (0.25, 0.48 and 0.66 mg/kg/week). Mean IGF-I approached 0 SD in the first month in the somatrogon group but with large interindividual variation, and at 12 months the mean IGF-I was +0.65 SD (range -3.3 to +3.2 SD) compared to a range of -0.69 to -0.16 in the once daily somatropin group at 12 months. Dose reductions were required in 2.2% of patients due to high IGF-I concentrations in the trial [2].

In a global Phase III study, once weekly **somapacitan** at 0.16 mg/kg/week demonstrated non-inferiority to once daily somatropin (0.034 mg/kg/day) in prepubertal children with GHD from 2.5 years of age [3], with similar increases in height velocity (11.2 vs 11.7 cm/year in somapacitan vs daily GH). Observed mean peak and trough IGF-I standard deviation score (SDS) levels during the somapacitan weekly dosing interval were +1.66 and -0.83, respectively. IGF-I SDS reached a maximum at 49-72 hours after somapacitan administration before declining to trough level on day 7 [4]. Peak IGF-I concentrations were above +2 SD in 27% vs 3.3% of patients in the somapacitan and daily GH group [3]. IGF-I concentrations on day 4 (97-120 hours) reflect average IGF-I over the week [4].

These trials included pre-pubertal children diagnosed with GHD defined as peak ≤10 ng/ml (which differs from the UK definition of peak <6.7 mcg/L [5] or equivalent assay specific level identified for each centre) and excluded patients with a prior history of cancer, intracranial tumours, treatment with chemotherapy or radiotherapy and syndromes e.g. Prader-Willi Syndrome. **We recommend caution if using somatrogon or somapacitan in patient groups with GHD not included in the Phase III studies e.g. Noonan Syndrome, Prader-Willi Syndrome, or patients with oncological disease, radio treatment or intracranial tumours. Somatrogon and somapacitan are not currently licenced or recommended for Turner syndrome, SGA with failure to catch up, chronic renal insufficiency and SHOX deficiency.**

<u>Guidance relating to both somatrogon and somapacitan</u>

- In overweight or obese patients, the clinician may want to consider using ideal body weight or body surface area rather than actual body weight to calculate the dose as no guidance regarding a maximum dose is available.

- Before starting growth hormone, we recommend testing for untreated central hypothyroidism and adrenocortical insufficiency.

- We recommend a minimum of 6 monthly evaluation of auxology and pubertal status and thyroid function 12 monthly.

- Consider bone age assessment every 12-24 months during treatment if there are medical concerns, or if assessing the growth potential in a young person considered to be near final adult height.

- The injection should be administered on the same day each week. However, the need for blood tests to assess IGF-I levels on day 4 (97 to 120 hours) after the injection should be taken into consideration.

- We recommend the assessment of IGF-I (97 to 120 hours after an injection) at 6 to 8 weeks after the initiation of treatment and then 4 to 6 monthly (4 days after an injection) thereafter, as a minimum.

- If a dose is missed within three days, it should be given as soon as possible, and the usual weekly dosing resumed on the usual day. If more than three days have passed, the missed dose should be skipped and the next dose given on the usual day.

- If the patient wishes to change the administration day, they should ensure that the time between any two doses is at least three days. They should be asked to discuss this with their clinician beforehand, to ensure that appropriate timing of blood tests remains.

Preparation specific guidance

Somatrogon

Somatrogon is comprised of the amino acid sequence of human growth hormone, with one copy of the C-terminal peptide (CTP) from the beta chain of human chorionic gonadotropin at the N- terminus and two copies of CTP at the C-terminus. It is currently approved as a once weekly subcutaneous injection for children over the age of three years with GHD until adult height has been reached [6]. Somatrogon has a half-life of 28 hours compared to 2-3 hours for somatropin.

Recommended dose and timing

- The recommended dose of somatrogon is 0.66 mg/kg/week.

- Pre-filled somatrogon injection pens are available as 24mg in 1.2 ml and 60 mg in 1.2 ml. For the 24 mg pen, the dose can be adjusted in 0.2 mg increments from a minimum dose of 0.2 mg to a maximum dose of 12mg. For the 60 mg pen, the dose can be adjusted in 0.5 mg increments from a minimum dose of 0.5 mg to a maximum dose of 30mg.

- If the patient's weight is >45 kg, two (or three if >90 kg) injections at different anatomical sites are needed. Written plans provided by the company can be helpful for administrating doses accurately and minimising wastage.

Recommended surveillance

- Serum IGF-I peaks on day 2 following the somatrogon injection and then decreases to low concentrations before the next injection [7]. The IGF-I concentration on day 4 (97 to 120 hours) following the injection reflects the average IGF-I over the week [7]. There are no validated calculators to generate an average IGF-I concentration from samples taken at time points other than day 4. The long-term effects of high IGF-I concentrations on days 2-3 are not known. Therefore, we recommend that day 4 IGF-I concentrations are kept within the normal range. For this reason, every effort should be made to ensure that the day of the injection is 4 days before the usual clinic day (and therefore the monitoring of blood tests).

- Mean IGF-I approached 0 SD in the first month in the somatrogon group but with large interindividual variation, and at 12 months the mean IGF-I was +0.65 SD (range -3.3 to +3.2 SD) compared to a range of -0.69 to -0.16 in the once daily somatropin group at 12 months. Dose reductions were required in 2.2% of patients due to high IGF-I concentrations in the trial [2].

- Dose adjustments should aim to achieve day 4 (97 to 120 hour) IGF-I SDS within the normal range (between -2.0 and +2.0 SDS but ideally close to 0 SD). To achieve this, the somatrogon dose can be reduced by 15% and IGF-I re-checked after 4-8 weeks. A further dose reduction of 15% may be required.

- In patients who have had the dose reduced but are not growing well, the dose may be gradually increased as tolerated up to a maximum dose of 0.66 mg/kg/week. Dose increments should not exceed the amount it had been reduced by (15% of the previous dose).

Monitoring of possible adverse events

- The most common adverse events were injection site pain (39.4% of somatrogon-treated *versus* 25.2% somatropin-treated), erythema (8.5% *versus* 0) and pruritus (5.5% *versus* 0)[2]. Clinical assessment should include monitoring for these.

- Currently, there are no data available on incidence of other side effects seen in once daily GH treatment such as intracranial hypertension and slipped upper femoral epiphysis. We recommend reporting any side effects through the Yellow Card Scheme https://yellowcard.mhra.gov.uk

- PROGRES was a post marketing surveillance study, and inclusion of patients treated with somatrogon was recommended where possible. The study is now complete and has been replaced by PROGRES 2.0 (on GloBE-Reg, July 2025 onwards). Participation will remain voluntary.

Somapacitan

Somapacitan is a GH derivative which has a change of one amino acid and a short non-covalent albumin binding moiety. Somapacitan therefore binds reversibly to albumin, prolonging its half-life, allowing for once weekly treatment. Somapacitan has a half-life of 34 hours compared to 2-3 hours for somatropin.

Somapacitan is licensed as a once weekly subcutaneous injection for children aged 3 years and above and adolescents with growth failure due to growth hormone deficiency (GHD), and for adults (18 years and older) where GH treatment is indicated for severe GHD. It is currently approved for GHD in children and adolescents 3-17 yr of age [8, 9].

Recommended dose and timing

- The recommended dose of somapacitan is 0.16 mg/kg/week

- In the UK, pre-filled somapacitan injection pens are available as 10 mg in 1.5 ml and 15 mg in 1.5 ml. For the 10 mg pen, the dose can be adjusted in 0.05 mg increments from a minimum dose of 0.05 mg to a maximum dose of 4 mg. For the 15 mg pen, the dose can be adjusted in 0.1 mg increments from a minimum dose of 0.1 mg to a maximum dose of 8 mg.

- If the patient's weight is > 50 kg, two (or three if > 100 kg) injections at different anatomical sites are needed. Written plans provided by the company can be helpful for administrating doses accurately and minimising wastage.

Recommended surveillance

- Serum IGF-I increases over the first 2-3 days after somapacitan injection and then decreases to a trough before the next injection [3, 4, 10-12]. An IGF-I sample taken 4 days (97-120 hours) after somapacitan best captures the weekly average [3, 4, 10, 11]. Therefore, we recommend that day 4 (97 to 120 hour) IGF-I concentrations are kept in the normal range. For this reason, every effort should be made to ensure that the day of the injection is 4 days before the usual clinic day (and therefore the monitoring blood tests).

- In REAL3 and REAL4 [3], the number of participants with an IGF-I SDS above +2.0 at two or more consecutive visits during the 52-week treatment period was 5 (3.8%) in the somapacitan-treated and 2 (2.9%) for the daily somatropin-treated. No patients had mean IGF-I SDS > +3 SDS, with most (96.6%) within the normal range (−2 to +2 SDS). IGF-I values for patients receiving daily GH in REAL 3 and REAL 4 were similar to those receiving somapacitan, showing a low proportion of patients with mean IGF-I > +2 SDS (1.2%), no patients with mean IGF-I > +3 SDS, and 95% patients achieving mean IGF-I within the normal range.

- One participant in each REAL4 group (0.8% for somapacitan and 1.4% for daily) required dose reductions due to IGF-I SDS > +2.5 at two consecutive visits.

- Dose adjustments should aim to achieve day 4 IGF-I SDS within the normal range (between -2.0 and +2.0 SDS but ideally close to 0 SD).

- If the IGF-I SDS is > 2, reducing the dose by 0.04 mg/kg/week is recommended [13]. Alternatively, IGF-I SDS can be reassessed after subsequent somapacitan administration. More than one dose reduction may be required in some patients.

- In patients who have had the dose reduced but are not growing well, the dose may be gradually increased as tolerated up to a maximum dose of 0.16 mg/kg/week. Dose increments should not exceed 0.02 mg/kg per week.

- GHD should be reassessed with a provocation test at the end of growth. If a decision is made to continue GH into young adulthood, then somapacitan can be continued until and including the age of 17. Once growth has completed, we recommend doses of somapacitan as stated in BNF for adults with GHD. Currently somapacitan is licensed for use in adults, but has no NICE/SMC approval for use in adults.

Monitoring for treatment-emergent adverse events

- The most common adverse events (observed in >5% participants in REAL4) were nasopharyngitis (16.7% of somapacitan treated *versus* 16.2% of daily somatropin-treated), headache (12.1% *versus* 8.8%), pyrexia (9.1% *versus* 11.8%), pain in extremities (9.8% *versus* 2.9%), injection site reactions (6.1% *versus* 5.9%), diarrhoea

(4.5% *versus* 5.9%), nausea/vomiting (4.5% *versus* 5.9%) and bronchitis (3% *versus* 7.4%). 1.5% in both the weekly somapacitan-treated (2/132) and the daily somatropin-treated (1/68) developed adrenocortical insufficiency. Most adverse events were judged unlikely related to the trial product.

- Other side effects may include peripheral oedema, hypothyroidism, arthralgia, hyperglycaemia and fatigue [13].

- Currently, there are no data available on incidence of other side effects seen in once daily GH treatment such as intracranial hypertension and slipped upper femoral epiphysis. We recommend reporting any side effects through the Yellow Card Scheme https://yellowcard.mhra.gov.uk

- REAL 10 is open for any clinicians/sites who have patients on somapacitan and would like to contribute to this post marketing registry. Registry will be part of GloBE-Reg, an international registry project working to improve global knowledge on drug effectiveness and long-term safety.

Long-acting growth hormone: Quick reference guide for clinicians initiating and monitoring treatment

	Somatrogon (Ngenla®)	**Somapacitan (Sogroya®)**
Before starting	Ensure no evidence of untreated central hypothyroidism or adrenocortical insufficiency.	Ensure no evidence of untreated central hypothyroidism or adrenocortical insufficiency.
Starting dose	0.66 mg/kg/week	0.16 mg/kg/week
Injection device dose increments	0.2 mg for 24 mg pens (max dose per injection 12 mg) 0.5 mg for 60 mg pens (max dose per injection 30 mg)	0.05 mg in 10 mg pens (max dose per injection 4 mg) 0.1 mg in 15 mg pens (max dose per injection 8 mg)
When to measure IGF-1	Day 4 (97-120 hours) after injection. Initially 6-8 weeks after starting, then every 4-6 months.	Day 4 (97-120 hours) after injection. Initially 6-8 weeks after starting, then every 4-6 months.
IGF-1 target range	-2.0 to +2.0 SDS	-2.0 to +2.0 SDS
Dose reduction for high IGF-1	Reduce by 15% and repeat IGF-1 in 4-8 weeks; reduce by a further 15% if required.	Initially reduce weekly dose by 0.04 mg/kg and repeat IGF1 in 4-8 weeks; More than one dose reduction may be required in some patients.
Poor growth in those requiring dose reduction	Gradually increase dose by a smaller amount than previous dose reduction, up to a maximum dose of 0.66 mg/kg/week.	Gradually increase weekly dose by 0.02 mg/kg, up to a maximum dose of 0.16 mg/kg/week.
Other monitoring	Perform auxology and consider pubertal staging every 4-6 months. Assess thyroid function every 12 months. Consider bone age assessment every 12-24 months if there are medical concerns.	Perform auxology and consider pubertal staging every 4-6 months. Assess thyroid function every 12 months. Consider bone age assessment every 12-24 months if there are medical concerns.

Missed dose management	*Within three days of usual day of injection*: give dose as soon as possible, and then continue dosing on usual day. *If more than three days since missed dose*: the missed dose should be skipped and the next dose given on the usual day.	*Within three days of usual day of injection*: give dose as soon as possible, and then continue dosing on usual day. *If more than three days since missed dose*: the missed dose should be skipped and the next dose given on the usual day.

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Appendix Patient information sheet developed by Dr Rebecca Moon and Prof Justin Davies, Southampton University Hospital.

Types of growth hormone therapy for children with growth hormone deficiency

Information for children, families and carers

We have given you this factsheet because your child has been diagnosed with growth hormone deficiency and your child's paediatric endocrinologist (doctor with expertise in looking after children and young people with hormone disorders) has recommended they start growth hormone therapy.

There are two different types of growth hormone available for children: daily (somatropin) and long acting (somatrogon and somapacitan). This factsheet provides an overview of both types of growth hormone. We hope that it will help you to make an informed decision about which growth hormone therapy suits your child best.
In addition to this factsheet, you will also have individual discussions with your child's paediatric endocrinologist. If you have any further questions or concerns, please contact us using the details at the end of this factsheet.

What is growth hormone deficiency?

Growth hormone deficiency is a condition where the pituitary gland (a pea-sized gland just below the brain) does not produce enough of a hormone (a chemical messenger) called 'growth hormone' which is needed for growth.

What is growth hormone therapy?

Growth hormone therapy is the treatment for growth hormone deficiency. It works by replacing the missing growth hormone with a synthetic (man-made) version. There are currently two types of growth hormone available for children.

Daily

This type of growth hormone has been used since 1985. It is given as a daily injection under the skin (subcutaneous), usually in the evening. There are several brands of daily growth hormone, but they all contain the same growth hormone (called somatropin).

Long-acting

This is a new type of growth hormone. There are currently two types of long-acting growth hormone available: Somatrogon (Ngenla®) and Somapacitan (Sogroya®). Long-acting growth hormone became available in 2023 for children (aged 3 to 17 years) who have a confirmed diagnosis of growth hormone deficiency. It is a subcutaneous injection but, unlike the daily injection, this long-acting growth hormone is given once a week.

What are the differences between the two types of growth hormone?

There are differences between the daily growth hormone and the long-acting growth hormone. To help you decide which option is right for your child, please see the table below for a comparison of the two types of growth hormone. We will provide training on how to give the type of growth hormone that you choose.

	Daily (somatropin)	Long-acting (somatrogon, or Ngenla® and somapacitan or Sogroya®)
How many injections and how/when are they given?	**One** injection every evening before bed.	**One to three** injections on one day each week depending on the weight of your child. • If your child weighs **less than 45kg (somatrogon)/50kg (somapacitan)**, the correct dose will usually be **one** injection. However, the last dose of medication in your child's injection device may not always be a full dose. If this is the case, you may need to give two injections for your child to get their full dose. You will need to inject the amount left in your injection device, then prepare a new pen to inject the rest of the dose on the same day. • If your child weighs more than **45kg (7 stone) for somatrogon or 50kg (7½ stone) for somapacitan**, they will need to have **two** injections at the same time on one day each week.
What monitoring and blood tests are required?	Your child will need occasional blood tests to check their growth hormone level, medically known as 'insulin-like growth factor-I (IGF-I)' and to monitor for other hormone deficiencies. These blood tests are usually not more than once a year and we do	Your child will need a blood test to check their IGF-I level 6 to 8 weeks after starting growth hormone. After this, they will need at least two blood tests each year. The blood sample must be collected four days after your child has had their weekly growth hormone injection (your clinic may be able to organise this for

	them during your child's scheduled clinic appointments. Your child will be seen in the outpatient clinic at least twice a year.	the same day as their clinic appointment). Your child will be seen in the outpatient clinic at least twice a year.
What injection devices are available?	You will be able to choose from several injection devices that we will arrange to show you. Each device will either have a liquid cartridge that is inserted into a pen or you will need to mix a powder with a liquid before use. We will show you how to use whichever device you choose.	Both somatrogon (Ngenla®) and somapacitan (Sogroya®) come in a pre-filled pen device. It does not need a cartridge to be inserted or pre-mixing.
How are the injections stored?	Most devices **must** be stored in a refrigerator and only taken out 30 minutes before giving the injection. They can be transported in cool bags for short trips (if needed).	Somatrogon (Ngenla®): The device **must** be stored in a refrigerator. Each pen can be kept at room temperature for up to four hours at a time (for a maximum of five times). Somapacitan (Sogroya®): The device **must** be stored in a refrigerator. Each pen may be kept temporarily at room temperature for up to a combined total of 72 hours (3 days).
Delivery and support	Whichever growth hormone you choose, it will be delivered to either your home or the hospital pharmacy by a home care delivery team. Your medical team will let you know the arrangements for this. You will have access to a dedicated support team for device training and arranging deliveries.	
Are there any side effects?	There are similar side effects for both types of growth hormone. Injection site reactions, such as: • itchiness • pain • redness • soreness at the injection site can happen with any growth hormone injection but have been reported more commonly with the long-acting growth hormone somatrogon (Ngenla®).	

What is known about the safety of the treatment?	Daily growth hormone is licensed and approved by the NHS. It has been used since 1985. Evidence-based research since this time has found the long-term use of daily growth hormone to be safe.	Long-acting growth hormone was licensed and approved for use by the NHS in 2023. The National Institute for Health and Care Excellence (NICE) UK has reviewed long-acting growth hormone to ensure it is as effective and safe as daily growth hormone. Safety of long-acting GH has been studied for 5 years in children but information on the longer-term safety of long-acting growth hormone after 5 years is not yet available. As with any new medication, there might be new side effects that appear as more people start to use it. If you choose long-acting growth hormone, it is important to tell us if your child experiences any unexpected side effects that we have not told you about.
Will my child need to continue this medication when they are older?	Growth hormone has other benefits as well as growth. For some people, we may recommend that they continue growth hormone therapy in adulthood. Daily growth hormone can be used to treat growth hormone deficiency in childhood and adulthood.	Somatrogon (Ngenla®) is only licensed for use during growth. If your child receives Ngenla® and we think that they would benefit from continuing growth hormone therapy after they have finished growing, they will need to switch to the daily growth hormone. We will discuss this with you if appropriate. Somapacitan (Sogroya®) is licensed for treatment of adult growth hormone deficiency but is not approved by NICE for use in adults in the NHS currently.

What happens next?

We hope that reading this factsheet has helped to answer some of your initial questions about growth hormone therapy treatment for your child.
You will be able to choose between the daily and long-acting treatment options. If you have a clear preference, please let us know when you contact us. If you are unsure, please let us know when you contact us, and a member of the team will be able to discuss this further with you.

What follow-up care is needed?

We will arrange regular follow-up appointments for your child. At each appointment, we will check whether the type of growth hormone your child is taking remains appropriate. We will adjust the dose, based on your child's weight, height, growth, and/or the results of their blood tests. If there are concerns about your child's response to the type of growth hormone you have chosen, it may be necessary to switch to a different type of growth hormone. Please note that if your child frequently misses growth hormone doses or frequently misses hospital appointments, we may not be able to continue prescribing this for them.

Contact us

If you have any further questions or concerns, please contact us.
Add centre contact details
If we are unable to answer your call, please leave a message with your name, your child's name and a brief message. We will aim to respond to your call or email within three working days.

Useful links

www.nice.org.uk/guidance/ta863/informationforpublic