Guidance on the use of growth hormone devices for children & adults

Approved by Scottish Paediatric Endocrine Group (SPEG) & Adult Scottish Endocrinology Interest Group
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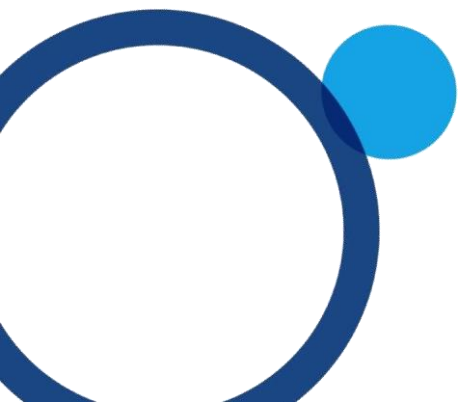
NOTE
This guideline is not intended to be construed or to serve as a standard of care. Standards of care are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge and technology advance and patterns of care evolve. Adherence to guideline recommendations will not ensure a successful outcome in every case, nor should they be construed as including all proper methods of care or excluding other acceptable methods of care aimed at the same results. The ultimate judgement must be made by the appropriate healthcare professional(s) responsible for clinical decisions regarding a particular clinical procedure or treatment plan. This judgement should only be arrived at following discussion of the options with the patient, covering the diagnostic and treatment choices available.



Purpose of Guidance

To provide a list of recommended products for Growth Hormone in line with NICE TA 188[1], NICE TA 64[2] and SPEG position statement on GH assessment and treatment during transition[3].

This guidance is for **new patients** across both paediatric and adult patient cohorts.

Background

Somatropin is recommended as a treatment option for children with growth failure associated with any of the following conditions:

- Growth hormone deficiency (GHD) in both adults and children
- Turner syndrome (TS)
- Prader–Willi syndrome (PWS)
- Chronic renal insufficiency (CRI)
- Born small for gestational age with subsequent growth failure at four years of age or later (SGA
- Short stature homeobox-containing gene deficiency (SHOXD)
- Growth failure due to Noonan syndrome.

NICE issued a technology appraisal guidance in May 2010 on somatropin human growth hormone (recombinant human growth hormone), for the treatment of growth failure in children (NICE TA 188).[1]

The following NICE Technology Appraisal and Position Statement provides guidance in prescribing Growth Hormone in Adults.

- NICE TA 64 Human growth hormone (somatropin) in adults with growth hormone deficiency[2]
- SPEG position statement on GH assessment and treatment during transition[3]

Supply of Growth Hormone in Scotland is initiated via Secondary Care, however the majority of patients are supplied in Scotland via Primary Care, through shared care arrangements with a small number of patients supplied via manufactured commissioned homecare.

There are six (6) suppliers who supply Somatropin in various injectable devices which vary in licensed indications, the cost of each brand varies (per mg). Most health boards will offer a range of 'preferred' devices to patients based on their treatment requirements, lifestyle and also personal preference to encourage adherence.

Key points of the NICE guidance TA188[1] are as follows:

Section 1.2 – Treatment with somatropin should always be initiated and monitored by a paediatrician with specialist expertise in managing growth hormone disorders in children. The choice of product should be made on an individual basis after informed discussion between the responsible clinician and/or their carer about the advantages and disadvantages of the products available, taking into consideration therapeutic need and the likelihood of adherence to treatment. If, after discussion, more than one product is suitable, the least costly product should be chosen.

Section 4.3.5 – The Committee heard…. that patient choice is an important factor in maximising adherence to therapy. However, the clinical specialists and patient experts highlighted that there appear to be no specific features that determine which product a patient will choose and that the choice of product depends in part on the choice of delivery system and the support package offered by the manufacturer. The Committee agreed that there appeared to be no differences in the clinical effectiveness of the various somatropin products available.

Section 4.3.13 – in light of the apparent equivalence of the clinical effectiveness of the different somatropin products, the least costly product that, after discussion between the responsible clinician

and the patient and/or their carer, has been agreed to meet the needs of the individual child and to maximise the likelihood of adherence to treatment should be chosen.

Product choice

The NICE TA 188[1] appraisal states that there appear to be no differences in the clinical effectiveness of the various somatropin devices although patient choice is an important factor in maximizing adherence to therapy[1]. Factors in choice of device may include the following; convenience, reliability, ease of use, lack of pain during injection, safety and acceptability to patients and the number of steps in preparation before, during and after usage. NICE TA188[1] states that if, after discussion with the patient and/or their carer, more than one product is suitable, the least costly product should be chosen.

NHS Scotland has conducted a procurement exercise to understand the most cost effective device considering factors such as price, storage, inclusion of nursing services and ancillaries offered by suppliers. The structure of the framework is an unranked multi supplier framework meaning that boards have a choice of what suppliers to select based on clinical/patient requirements.

In parallel with this process NHS Scotland is recommending devices aimed at new patients on a two tiered system based on the outcome of the procurement process based on the suppliers who scored highest from the process.

- Tier 1: Preferred product range for use in the majority of patients.
- Tier 2: Products for use in patients with specific needs.

This guidance is designed to ensure the following:

- Continued adherence to NICE guidance[1] with regards to patient choice as laid out in section 4.3.13.
- Inclusion of all Growth Hormone brands.
- Drive product rationalisation.
- Save nurse time by reducing the time spent discussing and demonstrating all brands with patients and families.
- Maintain a collaborative approach between prescribers and patients and/or carers, reserving the option to prescribe a growth hormone device from tier 2 based on the specific needs of individual patients or if it were felt this would improve adherence.

Recommendations

The following recommendations are made:

Supplier	Brand	Device	Tier 1	Tier 2
Novo Nordisk	Norditropin®	NordiFlex® FlexPro®	Preferred products range for use in the majority of patients	
Eli Lilly and Company Limited	Humatrope®	Humatrope® Pen		
Sandoz	Omnitrope®	SurePal®		
Pfizer Limited	Genotropin®	Genatropin Pen® Go Quick® Miniquick®		Products for use in patients with specific needs
Merck Serono	Saizen®	Easypod®		
Ipsen Ltd	NutropinAq®	NutropinAq® Pen		

Table 1: Recommendations

Key points implementing recommendations:

- Humatrope® - The price does not include nursing services. Therefore, Boards need to consider this if they are prescribing this device.
- Boards will be required to review how to implement tier 1 recommendations locally.
- Where required, the option remains open to prescribe a Growth Hormone device from tier 2 based on specific needs of individual patients or if it were felt this would improve adherence.
- Appendix A provides an overview of the main characteristic of each Growth Hormone Device. This may be used to support implementation of the guidance.
- Appendix B provides an overview of approved indications by supplier/brand. This may be used to support implementation of the guidance.

Appendix A: At-a-glance comparison of the main growth hormone device characteristics[4]

Supplier	Brand	Device	Cartridges for Injection Device	Pre-filled pen	Liquid Formulation	Room Temperature stable after reconstitution	Auto-Injection	Dose Present	Needle guard/cover	Dial back
Novo	Norditropin®	NordiFlex®	X	√*	√	√*	√	X	√	√
		FlexPro®	X	√*	√	√*	√	X	√	√
Eli Lilly	Humatrope®	HumatroPen®	√	X	X~	X	X	X	√	√
Sandoz	Omnitrope®	SurePal®	√	X	√	X	X	√	√	Xa
Pfizer	Genotropin®	Genotropin® Pen	√	x	X#	X	X	X	√	√
		GoQuick®	X	√	X#	X	X	√	√	√
		MiniQuick®	X	√	X#	√+	X	N/A	√	N/A
Merck	Saizen®	Easypod®	√	X	√	√**	√	√	√	N/A
Ispen	NutropinAq®	NutropinAq® Pen	√	X	X	X	X	X	√	√

Notes:

Reconstitution within the device (2-chamber cartridge);

~ diluent supplied separately;

+ can be kept at room temp for ≤6 months before use;

***** can be stored out the fridge for a maximum of 3 weeks below 25°;

** After first injection, can be stored in a refrigerator (2°C-8°C) for a maximum of 28 days, of which up to 7 days can be outside of a refrigerator at or below 25°C. When stored outside of the refrigerator for up to 7 days, the cartridge must be returned to the refrigerator and used within 28 days after first injection.

a the dose can still be changed without any wastage of the product if you dial above the correct dose, but reset is required;

Appendix B: Approved Indications [4]

Indication	Novo	Eli Lilly	Sandoz	Pfizer	Merck	Ispen
	Norditropin®	Humatrope®	Omnitrope®	Genotropin®	Saizen®	NutropinAq®
Growth hormone deficiency (GHD) Children	√	√	√	√	√	√
Growth hormone deficiency (GHD) Adult	√	√	√	√	√	√
Turner syndrome (TS)	√	√	√	√	√	√
Prader–Willi syndrome (PWS)	X	X	√	√	X	X
Chronic renal insufficiency (CRI)	√	√	√	√	√	√
Born small for gestational age with subsequent growth failure at four years of age or later (SGA)	√	√	√	√	√	X
Short stature homeobox-containing gene deficiency (SHOXD)	X	√	X	X	X	X
Growth failure due to Noonan syndrome	√	X	X	X	X	X

Note:

Reassessment is required on achievement of final height prior to considering ongoing therapy in adulthood for those started during paediatric care. Refer to SPEG position statement on GH assessment and treatment during transition[3]

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References

1. NICE technology appraisal guidance [TA188]. Published date: May 2010. Human growth hormone (somatropin) for the treatment of growth failure in children.
2. NICE technology appraisal guidance [TA64]. Published date: August 2023. Human Growth Hormone (somatropin) in adults with growth hormone deficiency.
3. SPEG position statement on GH assessment and treatment during transition.
4. Summary of Product Characteristics of the following brands; Available via www.medicines.org.uk (last accessed December 2020)

Supplier	Device
Novo	NordiFlex®
	FlexPro®
Eli Lilly	HumatroPen®
Sandoz	SurePal®
Pfizer	Genotropin® Pen
	GoQuick®
	MiniQuick®
Merck	Easypod®
Ispen	NutropinAq® Pen

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