Surrey Heartlands Integrated Care System
Area Prescribing Committee (APC)

Integrated Care Partnership - Surrey Downs, Guildford & Waverley, North West Surrey, and East Surrey Places & associated partner organisations.

NICE Technology Appraisals (TA) for local implementation

NICE TA Guidance name and number	Somatrogon for treating growth disturbance in people 3 years and over (TA863)		
Available at	https://www.nice.org.uk/guidance/ta863		
Date of issue	01 Feb 2023	**Implementation deadline**	03 March 2023 (30 days from publication)

Medicine details[1]	
Name and brand name	Somatrogon (Ngenla)
Manufacturer	Pfizer
Mode of action	Somatrogon is a glycoprotein comprised of the amino acid sequence of hGH with one copy of the of C-terminal peptide (CTP) from the beta chain of human chorionic gonadotropin (hCG) at the N-terminus and two copies of CTP (in tandem) at the C-terminus. The glycosylation and CTP domains account for the half-life of somatrogon, which allows for weekly dosing. Somatrogon binds to the GH receptor and initiates a signal transduction cascade culminating in changes in growth and metabolism. Consistent with GH signalling, somatrogon binding leads to activation of the STAT5b signalling pathway and increases the serum concentration of IGF-1. IGF-1 was found to increase in a dose-dependent manner during treatment with somatrogon partially mediating the clinical effect. As a result, GH and IGF-1 stimulate metabolic changes, linear growth and enhance growth velocity in paediatric patients with GHD.
Licensed indication	Ngenla® (somatrogon) is indicated for the treatment of children and adolescents from 3 years of age with growth disturbance due to insufficient secretion of growth hormone. Treatment should be initiated and monitored by physicians who are qualified and experienced in the diagnosis and management of paediatric patients with growth hormone deficiency (GHD). (accessed via SPC 01 Feb 2023)
Formulation	Solution for injection (injection). One mL of solution contains 50 mg of somatrogon. Each pre-filled pen contains 60 mg somatrogon in 1.2 mL solution. Each pre-filled pen delivers doses from 0.5 mg to 30 mg in a single injection in 0.5 mg increments. (accessed via SPC 01 Feb 2023)

Dosage	The recommended dose is 0.66 mg/kg body weight administered once weekly by subcutaneous injection. Each pre-filled pen is capable of setting and delivering the dose prescribed by the physician. Dose may be rounded up or down based on the physician's expert knowledge of the individual patient needs. When doses higher than 30 mg are needed (i.e. bodyweight > 45 kg), two injections have to be administered. Starting dose for patients switching from daily growth hormone medicinal products For patients switching from daily growth hormone medicinal products, the weekly therapy with somatrogon may be initiated at a dose of 0.66 mg/kg/week on the day following their last daily injection. **Dose titration** Somatrogon dose may be adjusted as necessary, based on growth velocity, adverse reactions, body weight and serum insulin-like growth factor 1 (IGF-1) concentrations. When monitoring for IGF-1, samples should always be drawn 4 days after the prior dose. Dose adjustments should be targeted to achieve average IGF-1 standard deviation score (SDS) levels in the normal **range**, i.e. between -2 and +2 (preferably close to 0 SDS). In patients whose serum IGF-1 concentrations exceed the mean reference value for their age and sex by more than 2 SDS, the dose of somatrogon should be reduced by 15%. More than one dose reduction may be required in some patients. (accessed via SPC 01 Feb 2023)
Comparison of NICE TA with Summary of Product Characteristics (SmPC)[2]	The dosage schedule is available in the summary of product characteristics for somatrogon. *This is the current dose considered by NICE as part of this NICE evaluation. Subsequent changes in the license following NICE publication will need to be considered by the Area Prescribing Committee and will not be routinely funded by local commissioners, as the incremental cost per QALY would not have been considered.*

NICE TA recommendations[2]

Recommendations

1.1 Somatrogon is recommended, within its marketing authorisation, as an option for treating growth disturbance caused by growth hormone deficiency in children and young people aged 3 years and over.

1.2 If people with the condition and their clinicians consider somatrogon to be 1 of a range of suitable treatments (including any preparation of somatropin) discuss the advantages and disadvantages of the available treatments. After that discussion, if more than 1 treatment is suitable, choose the least expensive. Take account of administration costs, dosage, price per dose and commercial arrangements.

Why these recommendations were made

Growth disturbance caused by growth hormone deficiency is usually treated with somatropin, available in multiple preparations, which are already recommended in NICE's technology appraisal guidance on somatropin. Somatrogon works in a similar way, but it is a weekly injection instead of a daily one.

Evidence from clinical trials shows that somatrogon is as effective as one preparation of somatropin (Genotropin).
The cost modelling used a range of dosages of somatropin (0.023 to 0.039 mg/kg per day), which clinical experts advised is the range of dosages used in the NHS.
Using this range of dosages, a cost comparison suggests the costs of somatrogon are similar to those of the somatropin preparations. So somatrogon is recommended.
For all evidence see the committee papers. To see what NICE did for somatropin, see the committee discussion in NICE's guidance on somatropin.

Decision making framework (DMF)

National guidance and priorities

The ICS has a legal obligation to commission this medicine in line with the NICE TA.

- This NICE TA has been assigned an implementation deadline *fast tracked to 30 days.*
- The implementation deadline is 03 March 2023*.*

Clinical effectiveness

- Evidence from clinical trials shows that somatrogon is as effective as one preparation of somatropin (Genotropin).

Patient safety

- The product should be used within its product license.
- Somatrogon will be provided with a comprehensive patient support program including starter kits, ancillary provision, homecare delivery and nursing, a patient helpline, and a patient website by the manufacturer (this patient support/homecare package is available to patients across primary and secondary care).
- Prescribers/medicine safety officers should pay due regards to medicine safety of switching patients from daily to weekly injections (risk of patient misadministration/overdosage).
- Prescribers/medicine safety officers should pay due regards to mis-selection of product during prescribing (EPMA). Note: all biological drugs which includes growth hormone should be prescribed by brand, as per good practice principles.
- Prescribers and pharmacy teams should be prepared to develop and accommodate a safe method to allow for a prescribing switch program. However, initiation of new product should be managed by appropriate secondary care physician as per SPC..

Patient factors

- Patients and carers would appreciate the option to be able to reduce the treatment burden of having to inject daily to a weekly treatment. The treatment burden of daily injections on children and their caregivers commonly leads to poor compliance, which increases over time and has a cumulative impact on key growth outcomes and QoL.
- This medicine is available under a homecare service so will be delivered directly to the patient. When the patient is confident in self-administering, this may reduce the number of hospital appointments to those required for review and/or monitoring.
- Somatrogon will be provided with a comprehensive patient support program including starter kits, ancillary provision, homecare delivery and nursing, a patient helpline, and a patient website by the manufacturer (this patient support/homecare package is available to patients across primary and secondary care).

Environmental impact

- The following would apply to patients new to use of growth hormone (somatropin or somatrogon) – any patients switching to somatrogon from somatropin would in fact be causing less of an environmental impact.
- Somatrogon is only available as an injection. It is likely that the product would be delivered to the patient's home via a dedicated homecare service using a refrigerated van - this could be considered as an **additional carbon load** due to extra road traffic **(increased air pollution** for new patients**).**
- **Medical sharps waste** would be collected and disposed of by the homecare company for incineration **(increased air pollution** for new patients**)**
- **Packaging waste** (for new patients) would be additional to usual municipal waste recycling or landfill.

- Discharge into the **wastewater** system (post-metabolism) from an individual patient is unlikely to have a significant impact short term, however the long-term impact to the water ecosystem is unknown.

Equality & diversity

NICE did not identify any negative impacts in their equality impact assessment, but noted the following:

Among children treated with rhGH for GHD, a higher frequency of boys than girls has been noted, and this is consistent throughout the world as well as over the period since rhGH became available in 1985. Boys are over-represented among referrals for short stature to general and specialist hospitals. A global appreciation of gender biases is required for the proper care of short girls.

With regard to GH treatments, several studies have evaluated the effects of socioeconomic status on adherence to prescribed GH therapy with mixed findings.

In a 2011 literature review, key drivers of poor GH adherence identified both psychological/emotional and social problems and stressed the interconnected nature of these factors to socioeconomic issues such as poverty, low education levels, and lack of social support. Since poor adherence to prescribed GH regimens is associated with decreased final height, children with pGHD who are socioeconomically disadvantaged may be less likely to achieve maximum adult height potential, possibly impacting quality of life (QoL) in the longer term. GH regimens with fewer doses and more convenient dosing requirements, such as long acting growth hormone (LAGH), could potentially help to improve adherence and outcomes among socioeconomically disadvantaged children.

Author has identified the following as having a possible negative impact on patients:

- **age** – somatrogon is only licensed for use from the age of 3 years until final growth is established as per SPC. It is not licensed for use past this point, in any age group.
- **Disability** – patients/carers who cannot use the injection device might be disadvantaged, although alternative ways to get the drug administered remain an option e.g. ancillary care.
- **Religion or belief** – vegans/vegetarians or those with strict ethical objections to the use of animal products would be unable to use somatrogon, which is of biological origin.

Note: Drugs approved by NICE for adult conditions will be commissioned in children at specialised paediatric centres if the patient meets the NICE criteria and there is evidence to suggest that the drug is safe and clinically appropriate to use in children as per the NHS England Medicines for Children Policy (see https://www.england.nhs.uk/publication/commissioning-medicines-for-children-specialised-services/ and a Blueteq form is available.

Place in therapy relative to available treatments

Other NICE recommended products[5]:

Table 25: ***Acquisition costs of the intervention and comparator technologies***

	Somatrogon	Humatrope®	Zomacton®	NutropinAq®	Norditropin®	Genotropin®	Omnitrope®	Saizen®
Pharmaceutical formulation	Solution for injection	Powder and solvent for solution for injection	Powder and solvent for solution for injection.	Solution for injection	Two pharmaceutical forms are available: 1. Solution for injection in cartridge 2. Solution for injection in pre-filled pen	Powder and solvent for solution for injection	Solution for injection in a cartridge	Two pharmaceutical forms are available: 1. Solution for injection in cartridge 2. Powder and solvent for solution for injection
(Anticipated) care setting	Primarily Hospital setting	Primarily Hospital setting	Primarily Hospital setting	Primarily Hospital setting	Primarily Hospital setting	Primarily Hospital setting	Primarily Hospital setting	Primarily Hospital setting
Acquisition cost (excluding VAT) *	24mg/1.2ml, 1=£189.60 60mg/1.2ml, 1=£474.00	6mg, 1=£108.00. 12mg, 1=£216.00. 24mg, 1=£432.00	1=£68.28	1=£203.00; 3=£609.00.	5mg/1.5ml, 1=£115.90. 10mg/1.5ml, 1=£231.80. 15mg/1.5ml, 1=£347.70	5.3mg, 1=£92.15. 12mg, 1=£208.65	5mg/1.5ml 5=£368.74. 10mg/1.5ml 5=£737.49. 15mg/1.5ml 5=£1106.22	5.83mg/ml, 1 x 1.03ml (6mg)=£139.08. 8mg/ml: 1 x 1.5ml (12mg)=£278.16; 1 x 2.5ml (20mg)=£463.60.
Method of administration	Subcutaneous injection	Subcutaneous injection	Subcutaneous injection	Subcutaneous injection	Subcutaneous injection	Subcutaneous injection	Subcutaneous injection	Subcutaneous injection
Doses	0.66mg/kg/week	0.025-0.035mg/kg/day	0.025-0.035mg/kg/day	0.025-0.035mg/kg/day	0.025-0.035mg/kg/day	0.025-0.035mg/kg/day	0.025-0.035mg/kg/day	0.025-0.035mg/kg/day
Dosing frequency	Once weekly	Once daily	Once daily	Once daily	Once daily	Once daily	Once daily	Once daily
Dose adjustments	In patients whose serum IGF-1 concentrations exceed the mean reference	N/A	Generally a daily injection of 0.02 – 0.03 mg/kg bodyweight or 0.7 - 1.0 mg/m^2 body surface area. The total	N/A	The dosage is individual and must always be adjusted in accordance with the individual's clinical and biochemical	Generally a dose of 0.025 - 0.035 mg/kg body weight per day or 0.7 - 1.0 mg/m² body surface area per day is	Generally a dose of 0.025 - 0.035 mg/kg body weight per day or 0.7 - 1.0 mg/m2 body surface area per day is	N/A

	value for their age and sex by more than 2 SDS, the dose of somatrogon should be reduced by 15%. More than one dose reduction may be required in some patients.		weekly dose of 0.27 mg/kg or 8 mg/m^2 body surface area should not be exceeded (corresponding to daily injections of up to about 0.04 mg/kg)		response to therapy.	recommended. Even higher doses have been used.	recommended. Even higher doses have been used.	
Average length of a course of treatment	Long-term; mean treatment length is 7 years (please refer to the economic model for treatment).[13] Cost comparison looks at the estimated annual treatment cost of an average patient, given all patient variable parameters will be consistent across all treatment options.							
Average cost of a course of treatment (acquisition costs only)	£7.90 per mg / £10,845 est. annual cost*	£18.00 per mg / £8,911 est. annual cost*	£17.07 per mg / £8,450 est. annual cost*	£20.30 per mg / £10,049 est. annual cost*	£21.27-£23.18 per mg / £11,475 est. annual cost*	£17.39 per mg / £8,609 est. annual cost*	£14.75 per mg / £7,302 est. annual cost*	£23.18 per mg / £11,475 est. annual cost*
(Anticipated) average interval between courses of treatment	N/A							
(Anticipated) number of repeat courses of treatment	Treatment should be discontinued when there is evidence of closure of the epiphyseal growth plates (see section 4.3). Treatment should also be discontinued in patients having achieved final height or near final height.	Treatment should be continued until the end of the growth has been reached.	The duration of treatment, usually a period of several years, will depend on maximum achievable therapeutic benefit.	Treatment should be continued in children and adolescents until their epiphysis are closed.	Patients should be re-evaluated for GH secretory capacity after growth completion. When GHD persists after growth completion, growth hormone treatment should be continued to achieve full somatic adult	Where childhood onset GHD persists into adolescence, treatment should be continued to achieve full somatic development (e.g. body composition, bone mass).	Where childhood onset GHD persists into adolescence, treatment should be continued to achieve full somatic development (e.g. body composition, bone mass).	Treatment should be discontinued when the patient has reached a satisfactory adult height or the epiphyses are fused.

					development including lean body mass and bone mineral accrual.			

*per mg cost taken from BNF; estimated annual cost based on daily dose of 0.034mg/kg (converted to weekly) and weekly dose of 0.66mg/kg/week (somatrogon) and average child weight of 40kg. Additional information:

1) The daily growth hormone dose of 0.034 mg/kg/day (equivalent to 0.24 mg/kg/wk) was chosen based on the most commonly used dose (0.24mg/kg/wk) worldwide in real world setting for pGHD, and is in line with the posology licensed for its use. This was also the dose investigated in the pivotal study for somatrogon.

2) Weight is estimated based on average mean weight of patient assuming linear growth in weight year on year. A change in weight is expected to have a proportionate change across all technologies.

Options not reviewed by NICE but used in standard practice:

n/a

- Somatropin and somatrogon are at the same place in therapy for GHD, choice is based purely upon whether a daily or weekly injection is preferred.
- Somatrogon's once a week injection therapy reduces injection frequency and burden and has been demonstrated to increase intention to comply with the weekly injection schedule compared to dGH.
- Patient preference studies have also shown that both patients and caregivers prefer a weekly injection over the current daily injection.
- Finally, an important aspect of the once a week versus daily injections is that it has the potential to positively impact paediatric patients' QoL through reduced life interference and treatment burden.

Stakeholder views

The paper was sent out for consultation and *x* comments were received.
Comments to be included in the front sheet.

Cost-effectiveness

The drug cost per Place according to NICE resources *exceeds/does not exceed* £100,000.
Are there any savings shown in the calculator?

Section 1: cost of the technology

a. Annual cost per patient (or complete course if shorter) for both primary and secondary care:

£166.08 per 1.2-ml vial containing 24 mg of somatrogon or £415.20 for a 1.2-ml vial containing 60 mg of somatrogon (excluding VAT, company submission, December 2022).

Annual cost per patient:

At the recommended dose of 0.66 mg per kg per week the estimated annual cost for a 40 kg patient is £9,500 (based on the above information). Costs may vary in different settings because of negotiated procurement discounts. However a NHS list price has been negotiated which is applied equally across both primary and secondary care.

Has dose escalation been considered as part of the NICE costing template?

Somatrogon dose may be adjusted as necessary, based on growth velocity, adverse reactions, body weight and serum insulin-like growth factor 1 (IGF-1) concentrations.

b. Availability of CAP/PAS price:

No. Nor does there appear to a CMU contract price.

However, Pfizer have confirmed that there is a NHS list price, which will be applied equally across primary and secondary care.

c. Price relative to comparable medicines:

NICE cost modelling used a range of dosages of somatropin (0.023 to 0.039 mg/kg per day), which clinical experts advised is the range of dosages used in the NHS.
Using this range of dosages, a cost comparison suggests the costs of somatrogon are similar to those of the somatropin preparations.

Table 26: ***Base-case results***

Technologies	Estimated Annual Acquisition costs (£)	Resource / Adverse event / Other costs (£)	TOTAL COSTS (£)	Market Share (%)[1]
Somatrogon	**£10,845**	**N/A**	**£10,845**	[redacted] %
Norditropin®	£11,475	N/A	£11,475	[redacted] %
Saizen®	£11,475	N/A	£11,475	[redacted] %
Nutropin AQ®	£10,049	N/A	£10,049	[redacted] %
Humatrope®	£8,911	N/A	£8,911	[redacted] %
Genotropin®	£8,609	N/A	£8,609	[redacted] %
Zomacton®	£8,450	N/A	£8,450	[redacted] %
Omnitrope®	£7,302	N/A	£7,302	[redacted] %

Annual treatment costs (12 months) based per patient

Section 2: NICE resource impact statement and template

NICE did not provide any cost calculators to commissioners.

a. NICE resource impact statement

No significant resource impact is anticipated

NICE has recommended somatrogon within its marketing authorisation, as an option for treating growth disturbance caused by growth hormone deficiency in children and young people aged 3 years and over.

If people with the condition and their clinicians consider somatrogon to be 1 of a range of suitable treatments (including any preparation of somatropin) discuss the advantages and disadvantages of the available treatments. After that discussion, if more than 1 treatment is suitable, choose the least expensive. Take account of administration costs, dosage, price per dose and commercial arrangements.

NICE does not expect this guidance to have a significant impact on resources; that is, the resource impact of implementing the recommendations in England will be less than £5 million per year (or approximately £9,000 per 100,000 population, based on a population for England of 56.3 million people).

This is because the technology is a further treatment option and the overall cost of treatment for this patient group will be similar.

This technology is commissioned by integrated care boards. Providers are NHS hospital trusts.

b. NICE resource impact template

NICE did not provide a cost calculator as part of its publication.

It is not known how many patients would want to move onto a once-weekly injection, although it is assumed that the uptake would be high.

Based on provided patient numbers from local provider Trusts, and ePACT, and assuming that **all** patients transition onto somatrogon over time, then there is a cost pressure of £213,674 for the system (with an average pressure of £54k per Place) if list price is used.

NICE states that some costs may vary in different settings because of negotiated procurement discounts, there is a NHS list price in place which will be applied equally across primary and secondary care.

See below for costs per Place, using NICE estimated costs.

Drug costs for Surrey Heartlands:

	NICE estimated costs	ES	G&W	NWSy	SD	Total
Genotropin	£8,609	£ 43,045	£ 77,481	£ 146,353	£ 94,699	£ 361,578
Humatrope	£8,911	£ -	£ -	£ -	£ 17,822	£ 17,822
Norditropin	£11,475	£ 57,375	£ 57,375	£ 252,450	£ 22,950	£ 390,150
NutropinAq	£10,049	£ -	£ 10,049	£ -	£ -	£ 10,049
Omnitrope	£7,302	£ 14,604	£ 36,510	£ 109,530	£ 175,248	£ 335,892
Saizen	£11,475	£ 11,475	£ 68,850	£ 11,475	£ 22,950	£ 114,750
Zomacton	£8,450	£ -	£ -	£ -	£ -	£ -
Unidentified	£11,475	£ 252,450	£ 11,475	£ 45,900	£ 57,375	£ 367,200
Total		£ 378,949	£ 261,740	£ 565,708	£ 391,044	£ 1,597,441
Cost if all patients move to somatrogon	£10,845	£ 379,575	£ 292,815	£ 639,855	£ 498,870	£ 1,811,115
Cost compared to current somatropin usage		£ 626	£ 31,075	£ 74,147	£ 107,826	£ 213,674

Commentary:
Although NICE states that a significant impact on resources is not expected, there is still a new cost pressure even though this may be below the £9,000 per 100,000 population threshold for NICE, as this TA represents a new line of treatment.

At £9,000 per 100,000 population, this represents:

	East Surrey	Guildford and Waverley	Surrey Downs	North West Surrey	Surrey Heartlands ICB
Population*	193,532	232,784	316,690	388,466	1,131,472
Cost	£17,418	£20,951	£28,502	£34,962	£101,832

* August 2022 population figures from NHS Prescription Services through ePACT.

The Surrey Heartlands Director of Pharmacy and Medicines Optimisation has delegated authority to enable the Committee to be a decision-making committee providing the impact of any single decision does not exceed £100,000 within an individual Place per annum. Decisions with a cost impact of over £100,000 within an individual Place per annum require authorisation from Surrey Heartlands Health & Care Professionals Committee at their next meeting. Exception to this will be for any decision made in relation to a NICE Technology Appraisal (which are subject to requiring mandatory funding by commissioners) and other urgent items. The exceptions will be taken to the next Executive Meeting (which meets weekly) for authorisation.

Traffic light recommendation to APC

NHS Payment Scheme (NHSPS) excluded high-cost drug:
Yes

Recommended traffic light status and rationale:
Somatropin is currently AMBER on PAD
To ensure equity of access the author suggests that somatrogon is made AMBER (secondary care to initiate and stabilise – supply at least first 3 months of treatment).

A pharma-sponsored patient support/homecare package is available to patients across primary and secondary care.

PAD definitions, available at: Traffic Light Status (res-systems.net)

Implementation

NICE TA implementation must be within *30* days of publication.

Actions to implement:

Primary care

- Primary care practices that prescribe somatrogon as part of a shared care agreement will have their budgets compensated appropriately as per established MMT Central Team budgetary ring-fence process.
- Prescribers/medicine safety officers should pay due regards to medicine safety due to mis-selection of drug during prescribing. Note: all biological drugs which includes growth hormone should be prescribed by brand, as per good practice principles.
- Prescribers and pharmacy teams should be prepared to develop and accommodate a safe method to allow for a prescribing switch program. However, initiation of new product should be managed by appropriate secondary care physician as per SPC.
- Patients currently using somatropin should **NOT** be referred into secondary care purely for switching purposes. Switching should take place during routine outpatient appointments.
- If agreed by APC, primary care prescribers may be asked to continue prescribing somatrogon as part of a shared care agreement, in a similar way to how somatropin is prescribed in primary care. A pharma sponsored homecare package is available which accepts electronic or paper FP10 prescriptions.
- Primary care prescribers should be aware that their patient is receiving somatrogon and ensure that this is recorded in the patient's notes in order to be alert to potential side-effects and interactions with other medicines prescribed in primary care. This will also ensure that GP records, which are accessed by other healthcare providers, are a true and accurate reflection of the patient's medication.

Secondary care

- Providers are NHS hospital trusts.
- Trusts to follow internal governance procedures to add to their formulary and initiate homecare.
- Specialists will be required to notify the high-cost drugs teams of initiation and response to treatment using the Blueteq® system.
- The initiation, administration and on-going treatment is managed by secondary care.
- Homecare arrangements are likely to be managed by the trust, unless shared care is agreed.
- Secondary care should initiate, prescribe and supply treatment as per shared care agreement (if agreed)
- Treatment should be initiated and monitored by physicians who are qualified and experienced in the diagnosis and management of paediatric patients with growth hormone deficiency (GHD).
- Prescribers who initiate therapy should develop/accommodate an especial approach to training patients/carers when switching from daily somatropin to weekly somatrogon (risk of misadministration / overdosage).
- Prescribers/medicine safety officers should pay due regards to medicine safety of switching patients from daily to weekly injections (risk of patient misadministration/overdosage).
- Prescribers/medicine safety officers should pay due regards to mis-selection of product during prescribing (EPMA). Note: all biological drugs which includes growth hormone should be prescribed by brand, as per good practice principles.
- Patients should be monitored (at 6- or 12-month intervals) and treatment discontinued as per the SPC.
- Prescribers and pharmacy teams should be prepared to develop and accommodate a safe method to allow for a prescribing switch program.
- Waste from switching from somatropin to somatrogon should be minimised where possible.
- Switching from somatropin to somatrogon will be managed by secondary care prescribers only. The initial switch program will be resource intensive, but patients should only be switched over during their routine appointments i.e. no new especial

appointments should be required. Primary care prescribers will be reminded of this.

ICS

- NICE TA implementation must be within 30 days of publication.
- This technology is commissioned by integrated care systems.
- Monitoring of patient should be at 6–12-month intervals, this may require a change in service provision at provider level. This could be offset by reduced prescription burden to prescribers.
- No saving on drug cost or non-drug activity is anticipated. No potential savings for out-patient appointments as somatrogon is an alternative treatment option.
- Providers are NHS hospital trusts. However, shared care between primary and secondary care prescribers might be the most appropriate way to ensure safe and appropriate prescription and supply to patients.

PAD and Joint Formulary

- Trusts to follow internal governance procedures to add to their formulary and initiate Homecare / shared care arrangement.
- If APC agrees that somatrogon is appropriate to be used as part of a shared care agreement, then this is to be developed at pace.

Proposed tick box forms

- Blueteq forms to be developed. Suggest light touch approach, form at initiation only.

Additional information required for Joint Formulary:

- *A tick box will be included here.*

References:

1 Summary of Product Characteristics. Available at: Ngenla 60 mg solution for injection in pre-filled pen - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk) Accessed 02 February 2023

2 NICE Technology Appraisal Guidance: Somatrogon for treating growth disturbance in people 3 years and over (NICE TA863) Accessed 01 February 2023. https://www.nice.org.uk/guidance/ta863

3 NICE Resource Impact Report: Available at: https://www.nice.org.uk/guidance/ta863/resources Accessed 01 February 2023

4 NICE Resource Impact Template: Not available. Available at: Accessed n/a

5 NICE TA863 Committee papers, accessed 02 Feb 23, TA863 committee papers (nice.org.uk)