

**THE  
DONCASTER & BASSETLAW**

# **Shared Care Protocol**

**For the Management of Children with Growth  
Hormone Disorders**

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**Doncaster & Bassetlaw Area Prescribing Committee**

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# Shared Care Protocol

## For the Management of Children with Growth Hormone Disorders

### Statement of Purpose

This shared care protocol (SCP) has been written to enable the continuation of care by primary care clinicians of children initiated on growth hormone by the consultant paediatricians at Doncaster and Bassetlaw NHS Teaching Hospitals Trust, where this is appropriate and in the patients' best interests. Primary care will only be requested to take over prescribing of growth hormone within its licensed indication unless specifically detailed otherwise below. Users should be aware that this document is guidance on the management of a condition, not a commissioning arrangement.

Once a stable medication regime has been established (usually 6 months), physical monitoring and prescribing of amber category drugs can be transferred to primary care with agreement.

### Responsibilities of the specialist clinician

- Diagnosis and assessment
- Initiation and stabilisation of drug therapy, usually but not exceptionally, a period of 6 months.
- Patient/ family education
- Ensure patient/carer is fully informed of potential benefits and side effects of treatment and is competent to administer the treatment
- Provide a comprehensive treatment package in addition to medications including education, training on medication administration, reporting problems, supply of consumables and appropriate information sheet(s)
- Write to the GP after every clinic visit detailing whether the medication regime should remain the same or be changed. Specify any products /dose or frequency changes. The GP will also be informed in writing if the drug therapy is no longer required
- Provide advice and support to GP on request
- Monitor side effects of medication.
- Report adverse events to the MHRA.
- Expert clinicians suggest that blood tests should not be viewed as routine but only performed when clinically indicated. This will however be undertaken by the secondary care services where appropriate.

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## Responsibilities of the primary care clinician

- Ensure that shared care arrangements are in place before transfer of treatment
- That the patient/carer is clear what is being monitored and by whom
- That the patient knows what significant adverse effects/events to report urgently and to whom they should report (specialist or GP)
- Confirm that proposed therapy is not contra-indicated because of concurrent therapy for other conditions the patient may be suffering from e.g. check drug-drug and drug-disease interactions
- Confirm the specialists have provided the patient/carer with appropriate information sheet(s) and that adequate support is provided for the safe administration of treatment
- Ensure clear arrangements are in place for back up, advice and support e.g. out of hours and/or when the consultant initiating therapy is not available
- Monitor treatment as stated in the shared care proforma
- Confirm with specialist which changes in these or other parameters should trigger urgent referral back to the specialist
- Seek specialist advice promptly as advised in the shared care protocol or if signs/symptoms of changes occur
- Report adverse events to the MHRA
- If the drug has a black triangle status or is unlicensed, all events should be reported even if causal relationship is not known or if the adverse event is already known about
- Also report adverse events to the consultant sharing the care of the patient
- Stop treatment on advice of specialist, or immediately if intolerable side effects occur provided that it is safer to do so than to continue this therapy and refer back specialist care.

## Responsibilities of Patients or Carers

- Discuss potential benefits and side effects of treatment with the specialist and GP, to identify whether they have a clear picture of these from the specialist and to raise any outstanding queries
- Check that where possible the specialists have provided a patient-held record or information sheet for monitoring and/or to alert other clinical staff to the treatment they are receiving
- Share any concerns they have in relation to treatment with the medicine with their specialist or GP
- Report any adverse effects to their specialist or GP whilst taking the medicine
- Report to the specialist or GP if they do not have a clear understanding of their treatment
- Participate in the monitoring of therapy and the assessment of outcomes, to assist health professionals to provide safe, appropriate treatment

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## Indication

Drug Class	Traffic light system classification		
	Green <sup>G</sup>	Amber <sup>A</sup>	Red <sup>R</sup>
Synthetic Human Growth Hormone		Somatrogon (Ngenla), Somatropin (Gentropin, Humatrope, Norditropin, NutropinAq, Omnitrope, Saizen, Zomacton)	

G – Prescribing initiated and retained In Primary Care

A – Prescribing initiated by specialist and passed to primary care when dose effective and stable – monitoring shared as specified in SCP

R – Prescribing initiated and retained by specialist – Prescribing monitoring performed in secondary care

There are no significant therapeutic differences between the preparations available but choice may be determined by patient preference for the injection technique required. Somatrogon has a longer half-life allowing once-weekly administration.

It is important that the brand used should only be changed by the specialist service since training in a new injection technique may be required.

## Selection of patients

### Diagnosis

Linear growth is influenced by a number of endocrinological factors but growth hormone (GH) plays a predominant role due to both direct and indirect effects on the epiphyseal growth plate. It also affects carbohydrate and lipid metabolism, nitrogen metabolism and the growth of tissue

Growth hormone deficiency can result from a number of causes; the common ones are given below. It may occur as an isolated deficiency or part of panhypopituitarism (TSH, ACTH, LH, FSH and/or diabetes insipidus).

<u>Congenital</u>	<u>Acquired</u>
<ul style="list-style-type: none"> <li>• Midline embryonic defect e.g. septo-optic dysplasia, cleft palate, absence or hypoplasia of the pituitary.</li> <li>• Genetic, usually autosomal recessive.</li> <li>• Occasionally x-linked or dominant.</li> <li>• Haemorrhagic infarction at birth.</li> </ul>	<ul style="list-style-type: none"> <li>• Tumours of the pituitary, hypothalamus</li> <li>• Head injury</li> <li>• Histiocytosis</li> <li>• Post irradiation to the head</li> <li>• Cranial or cranio-spinal irradiation in acute leukaemia.</li> <li>• Temporary failure due to emotional deprivation or hypothyroidism.</li> </ul>

### National Institute for Clinical Excellence Guidance (NICE)

Recombinant human growth hormone (GH) treatment is recommended for children with proven clinical diagnosis of growth hormone (GH) deficiency supported by appropriate auxological, biochemical and radiological investigations. GH treatment is recommended for children with Turner syndrome (TS) and Prader-Willi syndrome.

GH treatment is recommended for pre-pubertal children with chronic renal insufficiency (CRI) providing:

- nutritional status has been optimised
- metabolic abnormalities have been optimised
- steroid therapy has been reduced to minimum.

GH treatment should, in all circumstances, be initiated and monitored by a paediatrician with special expertise in the management of children with GH disorder.

After attainment of final height, GH therapy will normally be discontinued, but it should not be discontinued by default. The decision to stop treatment should either be made by a paediatrician with special expertise in the management of children with GH disorders in consultation with patient and carers, or therapy should be continued until re-evaluation by an adult endocrinologist has been undertaken. The transition to adult care for people with GH disorders will require a close collaboration between the responsible clinicians.

In children with CRI, GH treatment should be stopped after renal transplantation. It should not normally be re-started until at least 1 year after renal transplantation to allow time to ascertain whether catch-up growth will occur.

The full guidance is available via [NICE TA 188](#).

NICE guidance on somatogon can be found at [NICE TA 863](#).

## Dosage, Contra-indications, Side –effects, Monitoring

For contraindications or further information please see the current BNF for Children

<https://www.medicinescomplete.com/mc/bnfc/current/>

or summary of product characteristics for the individual drug <http://www.medicines.org.uk/>

Drug, dose & TLS listing	Adverse effects	Therapeutic monitoring	Consultant	Clinical relevant drug interactions
			GP	
<b>1. Synthetic Human Growth Hormone</b>				
<b>1.1 Somatropin (<i>Amber</i>)</b> (Gentropin, Humatrope, Norditropin, NutroinAq, Omnitrope, Saizen, Zomacton)				
<p>Most children receive growth hormone as a daily subcutaneous injection of somatropin in the evening, self administered or given by the parents</p> <ul style="list-style-type: none"> <li>• Turner's syndrome, sc injection 45–50 mcg/kg daily or 1.4 mg/m<sup>2</sup> daily</li> <li>• Deficiency of growth hormone in children, by sc or im injection, 23–39 mcg/kg daily or 0.7–1 mg/m<sup>2</sup> daily</li> <li>• Growth disturbance in short children born small for gestational age whose growth has not caught up by 4 years or later, by sc injection, 35 mcg/kg daily or 1 mg/m<sup>2</sup> daily</li> <li>• Prader-Willi syndrome, by sc injection 35 micrograms/kg daily or 1 mg/m<sup>2</sup> daily; max. 2.7 mg daily</li> <li>• Chronic renal insufficiency in children by sc injection, 45–50 micrograms/kg daily or 1.4 mg/m<sup>2</sup> daily (higher doses may be needed) adjusted if necessary after 6 months</li> <li>• Short stature homeobox-containing gene (SHOX) deficiency, 45–50micrograms/kg daily</li> </ul>	<ul style="list-style-type: none"> <li>• Benign intra-cranial hypertension has been rarely associated with the <u>onset of GH treatment</u>, but is reversible with discontinuation of treatment. (At this stage the consultant will still have prescribing responsibility.)</li> <li>• Fluid retention (peripheral oedema)</li> <li>• Hypothyroidism, insulin resistance</li> <li>• Lipohypertrophy may occur at injection sites. These should be rotated and so supervision of the injection sites with appropriate advice should be given as necessary</li> <li>• Occasional joint pains are described, but no permanent arthropathy has been reported.</li> <li>• Severe headache with vomiting should lead to immediate referral to hospital paediatrician for</li> </ul>	<p>Every 3 months for first year, then every 6 months</p> <ul style="list-style-type: none"> <li>• Height &amp; weight</li> <li>• BP</li> <li>• Stage of sexual development</li> <li>• Side Effects</li> </ul> <p>Annually</p> <ul style="list-style-type: none"> <li>• Thyroid function</li> </ul>	<ul style="list-style-type: none"> <li>• Corticosteroids-growth-promoting effect of somatropin may be inhibited by corticosteroids</li> <li>• Oestrogen- increased doses of somatropin may be needed when given with oestrogens (when used as oral replacement therapy)</li> </ul>	
		<ul style="list-style-type: none"> <li>• Side Effect</li> <li>• Compliance</li> </ul>		

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	further assessment.		
<b>1.2 Somatrogen (Amber) (Ngenla)</b>			
<p>Somatrogen has a longer half-life and can be administered as a weekly subcutaneous injection, self administered or given by the parents</p> <ul style="list-style-type: none"> <li>Treatment of children and adolescents from 3 years of age with growth disturbance due to insufficient secretion of growth hormone, by sc injection, initially 0.66mg/kg weekly.</li> </ul>	<ul style="list-style-type: none"> <li>Benign intracranial hypertension has been rarely associated with the <u>onset of GH treatment</u>, but is reversible with discontinuation of treatment. (At this stage the consultant will still have prescribing responsibility.)</li> <li>Fluid retention (peripheral oedema)</li> <li>Hypothyroidism, insulin resistance</li> <li>Lipohypertrophy may occur at injection sites. These should be rotated and so supervision of the injection sites with appropriate advice should be given as necessary</li> <li>Occasional joint pains are described, but no permanent arthropathy has been reported.</li> <li>Severe headache with vomiting should lead to immediate referral to hospital paediatrician for further assessment.</li> </ul>	<p>Every 3 months for first year, then every 6 months</p> <ul style="list-style-type: none"> <li>Height &amp; weight</li> <li>BP</li> <li>Stage of sexual development</li> <li>Side Effects</li> </ul> <p>Annually</p> <ul style="list-style-type: none"> <li>Thyroid function</li> </ul>	<ul style="list-style-type: none"> <li>Corticosteroids-growth-promoting effect of somatrogen may be inhibited by corticosteroids</li> <li>Oestrogen- increased doses of somatrogen may be needed when given with oestrogens (when used as oral replacement therapy)</li> </ul>
		<ul style="list-style-type: none"> <li>Side Effect</li> <li>Compliance</li> </ul>	

The details above are not a complete list and the BNF and the SPC remain authoritative

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## Interactions

See **current** BNF and the individual product SPC.

## Re-Referral guidelines

Tel: 01302 644290, if required.

## Ordering information

Can be ordered from the usual pharmaceutical wholesalers.

## Contacts for Support, education and information

Tel: 01302 644290

Email: [anuja.natarajan1@nhs.net](mailto:anuja.natarajan1@nhs.net)

## References

- NICE Guidance TA 188: Human growth hormone (Somatropin) for the treatment of growth failure in children May 2010 [NICE TA 188](#)
- NICE Guidance TA 863: Somatrogen for treating growth disturbance in children and young people aged 3 years and over Feb 2023 [NICE TA 863](#)
- British National Formulary for Children September 2020

Full list of side-effects is given in the appropriate summary of product characteristics (SPC), available from [www.emc.medicines.org.uk](http://www.emc.medicines.org.uk) .

<https://www.england.nhs.uk/wp-content/uploads/2018/03/responsibility-prescribing-between-primary-secondary-care-v2.pdf>

As stated under primary care responsibilities, they should communicate with the specialist to confirm the agreement and acceptance of the shared care prescribing arrangement. This may be through a separate transfer of care form or the form on the sample letter below.

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## Template letter to primary care prescriber

Dear Prescriber

RE: \_\_\_\_\_ DOB: \_\_\_/\_\_\_/\_\_\_\_ NHS: \_\_\_\_\_

Address: \_\_\_\_\_ Postcode: \_\_\_\_\_

Your patient is being started on treatment with growth hormone using Somatrogen/ Gentropin / Humatrope / Norditropin / NutropinAq / Omnitrope / Saizen / Zomacton / Ngenla (please delete as appropriate).

This treatment can be prescribed by primary care prescribers under the Traffic Light System under the “shared care” arrangements. This shared care protocol has been approved by the Doncaster and Bassetlaw Area Prescribing Group.

As part of shared care arrangements please can you monitor adherence and side effects to therapy when you review this patient. Will you also please undertake to prescribe for your patient?

The prescriber will be responsible for ensuring monitoring of the patient on the medication being prescribed as per this protocol.

*Please acknowledge you are happy to take on shared care by completing and returning the slip below to above address or by secure email to \_\_\_\_\_*

Do not hesitate to contact us if you have any concerns.

Yours sincerely

**Clinician’s Name**

**Clinician’s Title**

### IMPORTANT REMINDER

*The prescriber is responsible for monitoring the patient on the medication being prescribed*

RE: \_\_\_\_\_ DOB: \_\_\_/\_\_\_/\_\_\_\_ NHS: \_\_\_\_\_

Address: \_\_\_\_\_ Postcode: \_\_\_\_\_

I AGREE to take on shared care of this patient

I DO NOT AGREE to take on shared care of this patient

Signed \_\_\_\_\_

Practice \_\_\_\_\_

Date \_\_\_\_\_

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