Request to Share Care and Agreement Form

Growth Hormone (Somatropin) Use in Children
Shared Care Protocol: Guideline Number 2; Version number 1

This Request to Share Care provides Key Primary Care Information on responsibilities and monitoring. The aim is to support the GP to agree to share care arrangements. Refer to Full Shared Care Protocol for further information (page 4 onwards).

GP to review and must respond to provider Trust request to share care within 2 weeks using form provided on page 3.

For Completion by Specialist (with Shared Care Agreement Form)

Patient name……

DOB…… **OR**

NHS number……

Addressograph label

Drug(s) Dose and Route at handover: ……

Indication:

Date of first prescription by specialist: …… Patient weight (kg): ……

Estimated date for prescribing to be continued by the GP: ……..……

Next monitoring tests due and dates if not at 12 week monitoring: ……..
……..…….

Specialist additional comments/advice: ……..……..
……...

Key Primary Care Information (refer to Full Shared Care Protocol for further information)

GP RESPONSIBILITIES

- Consider request to shared care arrangements and prompt completion and emailed return of signed response to the specialist using the Shared Care Agreement Form within 14 days of its receipt.
- If shared care accepted prescribe somatropin once patient is clinically stable in line with protocol.
- Ensure no drug interactions with other medicines.
- Change dose or stop treatment in line with protocol and as advised by specialist.
- Ensure that somatropin treatment has been approved by the CCG for the patient. The CCG pharmaceutical adviser will usually send a confirmation email to the GP at the time of initial approval.
- If any concerns regarding any aspect of the shared care guidelines, to contact their CCG pharmaceutical adviser for further support and advice.
- Promptly seek advice from the supervising consultant if there are any clinical issues.
- If the GP still does not feel confident to take on shared care responsibility, to inform the hospital consultant as soon as practicable.
- Prescribe somatropin as advised by the supervising specialist as follows:
  - Brand name
  - Presentation
  - Strength/Size

- Dosage
- Quantity
- Date

- Ensure prescriptions are suitably supplied to the Homecare Company that deliver the somatropin injections in a timely manner. Instructions on the request for growth hormone (GH) to be delivered monthly to the patient *e.g. Saizen® cartridge 20mg/2.5mL, 0.8mg daily, 3 month supply and deliver to patient in monthly instalments*.
- Authorise repeat prescriptions until the next review. Beyond this period, the GP must confirm with the hospital specialist the treatment is to be continued or whether the stopping criteria apply prior to continuing prescribing.
- Check the patient/carer is aware of who is undertaking the monitoring and when treatments are to be reviewed and stopped.
- Monitor the patient's overall health and well-being and usage of somatropin.
- To ensure the patient and family have a clear understanding of the treatment.

MONITORING AND ACTIONS TO BE TAKEN

Monitoring Table – see GP monitoring highlighted in grey.

Test	Indication	Specialist pre-treatment baseline	Specialist during treatment initiation	GP ongoing monitoring	Specialist ongoing monitoring
IGF-1 concentration	Essential before starting, and to obtain funding for treatment	Lower end of normative range for sex and age (to be stated)		Not required by GP	√
Thyroid function test	Endocrinopathy	√		Not required by GP	
Growth Velocity	Assess response	√	√	Not required by GP	√
Fundoscopy	Raised intracranial pressure	√		Not required by GP	
Fasting glucose and insulin	Insulin insensitivity	If indicated	If indicated	Not required by GP	If indicated
Blood Pressure	Obesity	√	√	Not required by GP	√
Fasting lipids	Obesity; Family history	√	√	Not required by GP	√
Gonadotroph and corticotroph	Endocrinopathy; Delayed puberty	√		Not required by GP	If indicated

Action to be taken if Abnormal Result

Abnormal Result	Action to be taken by GP
	GP will be informed by specialist via letter

- The expectation is that this information along with the full protocol provides sufficient information to enable GPs to be confident to take on the clinical & legal responsibility for prescribing and monitoring.
- Prescribing and monitoring responsibility will only be transferred under this shared care protocol when:
  - Specialist has initiated treatment and prescribed/monitored treatment for initial stabilisation period.
  - Specialist has provided pre-treatment counselling and discussed patient responsibilities, preferences and obtained consent to shared care arrangements.
  - Specialist and patient have completed and signed the shared care agreement form (page 3).

Shared Care Agreement Form

This form is used to agree shared care between the specialist, patient and GP.

Specialist and patient agreement

By signing below we accept:

- the HMMC shared care principles (ENHCCG ; HVCCG) and
- the requirements and responsibilities defined in this drug specific shared care protocol

Specialist name:	**Patient name or addressograph label:**
Designation:	
Provider Trust:	
Direct telephone number:	
Email: **Email (for use by GP to respond to request to share care):**	
Date:	**Specialist Signature:**

Date:	**Patient Signature:**

GP response to shared care

Please return to specialist within two weeks of receipt of request to share care.

This form is to be completed by the GP who is requested to share care.

I agree to accept shared care for this patient as set out in this shared care protocol and HMMC shared care principles (ENHCCG / HVCCG) ☐

I do not accept shared care for this patient ☐

My reason(s) for not prescribing are given below:

_____

_____

Please note that GP agreement is voluntary, with the right to decline to share care if for any reason you do not feel confident in accepting clinical responsibility. Refusal should not be for financial reasons.

GP name:	**Practice address /stamp:**
Direct telephone number:	
Email:	
Date:	**GP Signature:**

Please return a copy of the completed form to the requesting specialist within two weeks of receipt of request to share care (preferably by email).

1. Specialist to retain copy in patient's hospital records.
2. Copy to be given to patient.
3. GP to retain copy in patient's notes.

Full Shared Care Protocol

Growth Hormone (Somatropin) Use in Children
Shared Care Protocol: Guideline Number 2; Version number 1

This full protocol provides prescribing and monitoring guidance. It should be read in conjunction with HMMC shared care principles, Summary of Product Characteristics (SmPC) and the BNFC.

BACKGROUND AND INDICATION(S) FOR USE

Growth Hormone (GH) or somatropin is available as a biosynthetic and biosimilar growth hormone, with a sequence identical to human pituitary GH and is of importance for the metabolism of lipids, carbohydrates and proteins. It stimulates linear growth, increases growth rate and maintains a normal body composition.

Treatment with GH/somatropin should always be initiated and monitored by a paediatrician with specialist endocrinology expertise in managing growth hormone disorders in children.

A patient with confirmed GH/somatropin deficiency and in an otherwise stable condition does not require frequent hospital supervision and will be reviewed in the endocrine clinic 2-3 times a year.

Biosynthetic GH has a good safety record and monitoring of response more frequently than every 3-6 months is not required. Dose adjustments may be required annually, and will be based on changes in height, weight and IGF-1 levels.

GH therapy is expensive and continuation has to be justified by objective evidence of accelerated growth rate and improvement of predicted final height as detailed in the NICE continuation criteria. The hospital paediatric department has facilities for this assessment and will provide regular updates on patient's response to treatment to GPs.

A minority of candidates for GH therapy have had, or continue to have complex health disorders requiring specialist management, e.g. children with a brain tumour, complex midline defects and multiple pituitary hormone deficiencies (MPHD). GP and specialist must discuss each case individually in order to agree on a treatment and shared care strategy and agree as to when treatment with GH is most appropriate e.g. when the patient is in remission and in line with local commissioning criteria & NICE recommendations.

DOSAGE, ROUTE OF ADMINISTRATION AND DURATION OF TREATMENT

Recombinant human Growth Hormone (r-hGH) is administered by subcutaneous injection or needle free transjection, on a nightly single injection basis, in order to mimic the normal physiology of GH secretion.

Treatment should be discontinued if any of the below criteria apply. Consultants should confirm this in writing to the GP following reviews.

- Poor response: growth velocity in the first 3 years of treatment <50% above baseline value for year 1, 2, 3 of treatment.
- Growth velocity is less than <2cm total growth in 1 year
- Final height is attained. Confirmation of final height: bone age is >14yrs (girls) or >16yrs (boys)
- Insurmountable problems with adherence
- For Chronic Renal Failure (CRF) patients only: following renal transplant

Condition	micrograms/m^2/ day	micrograms/kg/ day	Notes
GH deficiency	700-1000	25-35	Use upper of dosing scale for pubertal child
Turners Syndrome	1400	50	-
Chronic Renal Failure	1400	50	-
SHOX deficiency	1400	50	-
Prader-Willi Syndrome (PWS)	1000	35	-
Small for Gestational Age (SGA)	1000	35	-

Company	Brand	Presentation	Strengths of Presentation (mg and mL, where relevant)	Primary Care Cost (per mg of somatropin)
Pfizer	**Genotropin®**	Pen Cartridge	5.3mg and 12.0mg	**£17.39**
		GoQuick® prefilled multi -dose pen	5.3mg and 12.0mg	
		MiniQuick® single dose prefilled syringes	0.2mg up to 2mg (in increments of 0.2mg)	
Sandoz	**Omnitrope®**	SurePal device	5mg, 10mg, 15mg	**£14.75**
Eli Lilly	**Humatrope®**	Pen Cartridge	6mg, 12mg and 24mg	**£18.00**
Ferring	**Zomacton®**	Vial for needle free device (for use with ZomaJet 2® Vision device)	4mg	**£17.07**
		Vial for syringe (for use with ZomaJet Vision X® device)	10mg	
Ipsen	**Nutropin Aq®**	Pen Cartridge	10mg	**£20.30**
Novo Nordisk	**Norditropin®**	SimpleXx® Pen Cartridge (for use with Nordipen®device)	5mg, 10mg and 15mg (all 1.5mL cartridges)	**£21.27**
		Nordiflex® prefilled multi -dose pen	5mg/1.5mL, 10mg/1.5mL, 15mg/1.5mL;	**£23.18**
Merck Sereno	**Saizen®**	Pen Cartridge (for use with cool.click® or easypod device®)	6mg/1.03mL , 12mg/1.5mL and 20mg/2.5mL	**£23.18**
		Click.easy® cartridge (for use with one. click® or cool.click® or easypod device®)	8mg	
Prices accessed from NHS Dictionary and Medical Devices (DM&D) August 2020				

SPECIALIST RESPONSIBILITIES INCLUDING PRE-TREATMENT ASSESSMENT

- Confirm a diagnosis for which GH treatment is recommended in line with NICE guideline.
- Ensure no contraindications to treatment with GH.
- To seek funding approval (using the agreed process) from the patient's CCG for commencement of GH treatment and at annual reviews thereafter.
- Initiate treatment and prescribe treatment for a minimum of 3 months.

	Product license for use in children					
Product	**Growth Hormone Deficiency**	**Turner Syndrome**	**Chronic Renal Insufficiency**	**Prader-Willi Syndrome**	**Growth Disturbance in SGA**	**SHOX deficiency**
Omnitrope®	Yes	Yes	Yes	Yes	Yes	No
Norditropin ®	Yes	Yes	Yes	No	Yes	No
Saizen®	Yes	Yes	Yes	No	Yes	No
Humatrope ®	Yes	Yes	Yes	No	Yes	Yes

- Obtain agreement and consent to share care. Complete and sign Specialist and patient agreement section of Shared Care Agreement form. Document in patient's notes and transfer once patient stabilised.
- Request for GP confirmation of acceptance of shared care by secure emailing of request to share care, protocol and completed agreement form, allowing 2 weeks for response.
- Receipt and recording in patient records/notes that GP has / has not accepted shared care and ensuring appropriate action if not (specialist to continue to prescribe/monitor).
- Prescribe and monitor for initial stabilisation period of 12 weeks.
- Six-monthly outpatient reviews, sending a written summary to the GP whenever the patient is reviewed.
- Monitor response to treatment, adverse effects and need to continue therapy. Notify the GP of any changes to dose, cessation of therapy or managing side effects.
- Notify GP if patient does not attend clinic and advise on action to take.
- Provide any other advice, information or support for the GP, if required. Communicate any clinically important issues and action to be taken.
- Discuss treatment with patient and ensure they have a clear understanding of it, including potential benefits, side effects, stopping criteria as well as practical issues related to the use of medication.
- Arrange training of patients and carers for the administration of the GH. The carer/child is involved with the choice of administration device.
- Check for concordance with medication and review GH dosage guided by height velocity, weight/surface area, pubertal stage and plasma IGF-1 concentration.

GP RESPONSIBILITIES

Refer to page 1-2 and GP Considerations for Shared Care (page 10).

PATIENT RESPONSIBILITIES IN COOPERATION WITH SPECIALIST AND GP

- Confirm their agreement with the decision to move to a shared care model for their ongoing care and their understanding of the shared care agreement.
- Consent to share care and complete/sign Specialist and patient agreement section of Shared Care Agreement form.
- Confirm their understanding of the treatment and agreeing to contact the specialist/GP if they subsequently do not have a clear understanding of the treatment (patient to be provided with relevant contact details for GP/specialist in and out of hours).
- Following training by a specialist nurse, the carer or child will administer GH by subcutaneous injection each night, in order to mimic the normal physiology of GH secretion. The injection site should be rotated in order to avoid lipotrophy.
- Attending for monitoring and follow-up hospital or GP appointments.
- Ensuring a list of all medications is brought to all GP surgery, outpatient and A&E consultations.
- Reporting any change in symptoms and adverse effects promptly to the clinician who is currently prescribing.
- Confirm that no new medicines are started (including over the counter preparations) unless this has been discussed with the GP, specialist or pharmacist.
- Alert GP and/or specialist of any changes of circumstance which could affect management of disease e.g. plans for pregnancy; plans to move/change GP practice.

DISPENSING PHARMACIST RESPONSIBILITIES

- Treatment to be suppled via a Homecare company and supplied directly to the patient on a monthly basis.

MONITORING AND ACTIONS TO BE TAKEN

Refer to page 2.

SIDE EFFECTS AND ACTIONS TO BE TAKEN (REFER TO BNF AND SmPC for full details)

GP to liaise with specialist if any side effects are a cause for concern.

Side Effect	Symptoms/signs	Action
Transient local skin reactions at injection site	Redness, inflammation	Rotate injection sites
Fluid retention, uncommon in children. More common in Turner Syndrome	Peripheral oedema	May subside spontaneously or dose reduction may be required - discuss with endocrine consultant
Arthralgia	Pain in joints	Start appropriate analgesia
Myalgia; may be related to the preservative m-cresol, a preparation without this preservative can be substituted	Pain or inflammation of voluntary muscle	Start appropriate analgesia
Hypo/Hyper-glycaemia	Hypo: hunger, nausea, sweating, weakness, faintness, confusion hallucinations, headache, cold sweat, piloerection, hypothermia, irritability, bizarre behaviour and fainting Hyper: thirst, polyuria, tiredness, and increased susceptibility to infections	Check blood glucose and if less than 2.6mmol/l or above 11.1mmol/l, specialist to review.
Benign intracranial hypertension	Severe/recurrent headache, visual problems, nausea/vomiting	Stop treatment immediately and urgently discuss with Endocrine consultant, fundoscopy for papilloedema is recommended.

CONTRAINDICATIONS AND PRECAUTIONS (REFER TO BNFC AND SmPC for full details)

- In diabetic patients, insulin doses may need to be adjusted on GH initiation.
- Children with Prader-Willi Syndrome (PWS) and Chronic renal failure (CRF) are managed at tertiary centres e.g. Great Ormond Street Hospital.

NOTABLE DRUG INTERACTIONS (REFER TO BNFC AND SmPC for full details)

- May increase clearance of drugs metabolised by cytochrome p450 3A4 e.g. anticonvulsants and ciclosporin.
- Corticosteroids may inhibit growth-promoting effects of somatropin.
- Higher doses of somatropin may be needed in patients on oral oestrogen replacement therapy.

CONTACT DETAILS for BACK-UP INFORMATION / ADVICE

	WHHT	E&NHT
Contact Details *(provide details of different sites where applicable)*	**Dr Vasanta Nanduri** Consultant Paediatrician **Dr Heather Mitchell** Consultant Paediatrician	**Dr Cristina Matei** Consultant Paediatrician **Dr Gunjan Jain** Endocrinology Special Interest **Dr Stephanie Jones** Endocrinology Special Interest
Direct dials for clinicians *(and nhs.net e-mail where available)*	01923 217391	01438 284437
Specialist Team designated nhs.net email	vnanduri@nhs.net Heather.mitchell@nhs.net	
Out of hours contact	Paediatric registrar on call	Paediatric registrar on call
Pharmacy Team shared care admin nhs.net email	wherts-tr.paediatricpharmacist@nhs.net	
Switchboard		

Communication

For any queries relating to this patient's treatment with somatropin, please contact the specialist as documented at the top of this document. Read in conjunction with HMMC shared care principles document. For advice if you have any concerns contact the specialist team. If unable to contact specialist team or out of hours, contact paediatric registrar on call.

SUPPORTING INFORMATION

Growth hormone (GH) deficiency (Idiopathic isolated GH deficiency; Congenital hypopituitarism; Acquired hypopituitarism)

- Somatotropin should be started as clinically indicated.

Turner Syndrome

- Somatotropin should be considered from 2 years of age.

Chronic renal failure (CRF)

- Nutritional support and metabolic abnormalities must be optimised
- Steroid therapy should be reduced before starting somatotropin
- Post renal transplant is a discontinuation criterion in the product SPCs.

Short stature homeobox-containing gene (SHOX) deficiency

- Somatotropin should be prescribed for patients who have growth failure associated with SHOX deficiency, as confirmed by DNA analysis.

Prader-Willi Syndrome (PWS)

- Somatotropin should be considered from >18months until bony epiphyses fused.
- Energy restricted diet should be implemented.
- We do not advocate treatment of obese patients with PWS, due to concerns about fatalities without careful evaluation by sleep studies and ENT.

Small for Gestational Age (SGA)

- Over 4 years of age and birth weight on or below 0.4th centile
- More than 2SD below the average height for age (below the 3rd centile after the age of 5)
- More than 2.5SD below the parental adjusted height standard deviation score (child's centile is more than 2.5 centiles less than the mean parental height centile)
- Height velocity standard deviation score is less than 0 over the past year (child falling below their centile over the last year).

There are other disorders in which GH therapy may be indicated as an off label usage, including Noonan syndrome, and skeletal dysplasias, IGF-1 Deficiency for example due to neurosecretory dysfunction and CHARGE syndrome with short stature and IGF1 deficiency. These indications ALL require approval via the Individual Funding Route (IFR).

REFERENCES

(1) BPSED Clinical Committee. Shared Care Guidelines: Paediatric use of Recombinant human Growth Hormone (r-hGH, Somatropin). May 2012, Reviewed July 2015.
https://www.bsped.org.uk/media/1377/sharedcaregh_july2015.pdf

(2) National Institute for Health and Care Excellence (NICE). Human growth hormone (somatropin) for the treatment of growth failure in children (TA188). May 2010.
https://www.nice.org.uk/guidance/ta188

(3) NHS England: Primary Care Delivery: Policy & Strategy, Operations & Information. Responsibility for prescribing between Primary & Secondary/Tertiary Care Version number 1.0. January 2018. https://www.england.nhs.uk/wp-content/uploads/2018/03/responsibility-prescribing-between-primary-secondary-care-v2.pdf

(4) The Nottinghamshire APC. Growth Hormone (Somatropin) in children and young people. September 2015.
https://www.nottsapc.nhs.uk/media/1013/growth-hormone-information-sheet.pdf?UNLID=

(5) West Essex Clinical Commissioning Group. Shared Care Guidelines Growth Hormone in Children. June 2016.
https://westessexccg.nhs.uk/your-health/medicines-optimisation-and-pharmacy/high-cost-drug-policies-and-pro-formas/growth-hormone/child/206-shared-care-guidelines-gh-children-june-14/file

GP Considerations for Shared Care

This shared care agreement outlines suggested management for the prescribing of the specified drug(s) and indication(s) when the responsibility is shared between the specialist and general practitioner (GP). Sharing of care assumes communication between the specialist, GP and patient. It is important that patients are consulted about treatment and are in agreement with it. The intention to share care should be explained to the patient by the doctor initiating treatment and consent obtained.

Prescribing is to be initiated in secondary care by a provider Trust specialist and will usually be prescribed for 12 weeks unless otherwise stated within the agreed individual shared care protocol**. The expectation is that these shared care guidelines should provide sufficient information to enable GPs to be confident to take on the clinical and legal responsibility for the prescribing and the monitoring of this / these drug(s) in stable patients.** The questions below will help you confirm this:

- Is the patient's condition predictable or stable?
- Do you have the relevant knowledge, skills and access to equipment to allow you to monitor treatment as indicated in this shared care document?
- Have you been provided with relevant clinical details including monitoring data?
- Have this document and BNF/SmPC provided sufficient information for you to feel confident in accepting clinical and legal responsibility for prescribing?

If you can answer YES to all of these questions (after reading this shared care guideline), then it is appropriate for you to accept the prescribing responsibility. GPs need to formally accept shared care by completing and returning the form provided within this protocol to the specialist within two weeks of receipt of request to share care.

If the answer is NO to any of these questions, you should not accept prescribing responsibility. You should respond back to the consultant outlining your reasons for NOT prescribing on the agreement form within two weeks of receiving the request to share care. If you do not have the confidence to prescribe, you still have the right to decline. In such an event, the total clinical responsibility for prescribing the medication and any monitoring required remains with the specialist. Please note that medication cost is not an acceptable reason for refusal to take on shared care.

The prescribing doctor legally assumes clinical responsibility for the drug and the consequences of its use as well as responsibility of monitoring (securing and reviewing blood test results).

Prescribing and monitoring responsibility will only be transferred when the consultant and the GP agree that the patient's condition is stable or predictable. This will usually be 12 weeks of treatment unless otherwise stated within the agreed individual shared care protocol.

Approval Information

Title of Guideline	Growth Hormone (Somatropin) Use in Children Shared Care Protocol
Guideline Number	2
Version	1
Effective Date	**October 2020**
Review Date	**October 2023**
Original Version Produced	N/A
Approvals:	
Provider Trust Drug / Formulary Management Group (e.g. MUSP, TPC)	WHHT MUSP – September 2020
Hertfordshire Medicines Management Committee	October 2020
Author/s	West Hertfordshire Hospitals NHS Trust Pharmacy department and relevant specialists supported by Hertfordshire CCGs Pharmacy and Medicines Optimisation Teams
Department(s) responsible for updating the guideline	West Hertfordshire Hospitals NHS Trust Pharmacy department and relevant specialists supported by Hertfordshire CCGs Pharmacy and Medicines Optimisation Teams