DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE
SHARED CARE AGREEMENT

Synthetic Human Growth Hormone (SOMATROPIN) / Long acting growth hormone (Somatrogon)

1. REFERRAL CRITERIA

- Shared Care is only appropriate if it provides the optimum solution for the patient.
- Prescribing responsibility will only be transferred when it is agreed by the consultant and the patient's GP that the patient's condition is stable or predictable.
- Safe prescribing must be accompanied by effective monitoring
- Patients will only be referred to the GP once the GP has agreed in each individual case, subject to receiving the relevant clinical information.
- Once stable the patient will be given a supply of somatropin sufficient for 4 weeks maintenance therapy.

2. AREAS OF RESPONSIBILITY

GP responsibilities	Consultant/specialist responsibilities
1. Reply to the request for shared care as soon as practicable. **2.** Prescribe growth hormone by brand and at the dose recommended by the specialist **3.** Report to and seek advice from the specialist on any aspect of patient care that is of concern to the GP and may affect treatment. **4.** Report any adverse effects to the referring specialist and the MHRA yellow card scheme. **5.** Stop treatment on advice of specialist.	**1.** Selection of patients suitable for treatment **2.** Discuss benefits and side effects of treatment with the patient and parent/carer **3.** Recommend starting dose, brand of drug and advise on subsequent dose changes **4.** Provide clear written information to the GP about ancillary equipment e.g. needles (brand/size) required to allow GP to continue to prescribe. **5.** Ensure the parent/carer understands when and how to give the medication **6.** Ask the GP whether he or she is willing to participate in shared care. **7.** Review the patient's condition and monitor response to treatment regularly (at least annually) as per section vi. **8.** Advise GPs on when to stop treatment. **9.** Report any adverse effects to the MHRA yellow card scheme and GP. **10.**Ensure clear arrangements for GP back-up, advice and support **11.** Re-assessment and transfer to adult endocrine care where necessary

Patient responsibilities

- Report any adverse effects to the specialist or GP whilst taking somatropin/somatrogon
- Share any concerns in relation to treatment with somatropin/somatrogon
- To administer somatropin/somatrogon as directed by the consultant/specialist
- Report to the consultant/specialist or GP if they do not have a clear understanding of their treatment

3. COMMUNICATION AND SUPPORT

i. Hospital contacts:

Paediatrics

Dr Tracy Tinklin, Consultant Paediatrician with an interest in diabetes and endocrinology.
UHDB – 01332 786824
Dr Denvir, Dr Randell, Dr Sachdev- Consultant Paediatric Endocrinologists, Nottingham University Hospitals
Paediatric Endocrine Nurse specialist Lisa Hill– 07471 140587

Adults

Consultants in Endocrinology

Dr Roger Stanworth, Dr Iskandar Idris, Dr Supreeth Rudrappa, Dr Luckni Sellahewa, Dr Antonia Uger – 01332 783283
Dr Paru King, Dr Hisham Ali – 01332 783284– 01332 783283
Dr Suma Sugunendran – 01332 783286
Dr David Hughes, Dr Emma Robinson – 01332 787696

Endocrine Nurse Specialist Rebecca Kinton, Elizabeth Mo, Sadaf Ulnasah – 07557 480441
ii. Out of hours contacts and procedures: On call Pharmacist 01332 340131 Bleep 1395
iii. Specialist support/resources available to GP including patient information: **Paediatrics** NICE TA 188 - Human growth hormone for the treatment of growth failure in children BPSED Treatment of Children with Recombinant Human Growth Hormone, shared care (December 2023) BNFC https://bnfc.nice.org.uk/ NICE TA 863 – https://www.nice.org.uk/guidance/ta863 Somatrogon for treating growth disturbance in children and young people aged 3 years and over (01/02/2023) **Adults** NICE TA 64 Human growth hormone in adults with growth hormone deficiency
iv. Local arrangements for referral- As outlined in the GP and consultant/specialist areas of responsibility.

4. CLINICAL INFORMATION

i. Prescribed indications	Children • Gonadal dysgenesis (Turner syndrome) in children • Growth hormone deficiency in children • Growth disturbance in short children born small for gestational age (SGA) whose growth has not caught up by age 4 years or later • Prader-Willi syndrome in children • Chronic renal insufficiency in children before puberty • SOMATROGON is only licensed for treatment of children and adolescents from 3 years of age with growth hormone deficiency **NB Due to lack of availability of licensed preparation for short stature homeobox containing gene (SHOX) deficiency this indication is not suitable for shared care and prescribing responsibility will remain with the consultant.** Adult • Adult growth hormone deficiency defined as a peak GH response of less than 9 mU/litre (3 ng/ml) during a glucagon stimulation test (or insulin tolerance test). • Growth hormone deficiency in adults <25 years old who have not attained peak bone mass and who have severe growth hormone deficiency as above.
ii. Therapeutic summary	All somatropin products are licensed for the treatment of short stature due to an inadequate secretion of growth hormone, for use in Turner Syndrome, chronic renal insufficiency and growth disturbance in short children born SGA, except Nutropin Aq® which is unlicensed for use in SGA. Genotropin® and Omnitrope® are also licensed for use in Prader-Willi syndrome. Somatrogon is only licensed for children aged 3 years and over with growth hormone deficiency

iii. Dose & Route of administration	As per NICE guidance: Treatment with a somatropin/somatrogon should always be initiated and monitored by a specialist with expertise in managing growth hormone disorders. The choice of a product should be made on an individual basis after informed discussion between the responsible clinician and the patient and/or carer about the advantages and disadvantages of the products available, taking into consideration therapeutic need and the likelihood of adherence to treatment. If, after that discussion, more than one product is suitable, the least costly product should be chosen. **Somatropin** Gonadal dysgenesis (Turner syndrome) 45-50 micrograms/kg daily or 1.4mg/m^2 daily Growth hormone deficiency in children 23-39 micrograms/kg daily or 0.7-1mg/m^2 daily Growth disturbance in children born small for gestational age (SGA) whose growth has not caught up by 4 years of age or later 35 micrograms/kg daily or 1mg/m^2 daily Prader-Willi syndrome 35 micrograms/kg daily or 1mg/m^2 (maximum 2.7mg daily) Chronic renal insufficiency in children before puberty 45-50 micrograms/kg daily or 1.4mg/m^2 daily Adult growth hormone deficiency 150-300 micrograms daily gradually increasing to 1mg daily **Somatrogon** Growth hormone deficiency 0.66mg/kg once weekly
iv. Treatment duration	Indefinite or as per monitoring requirements below
v. Pregnancy, paternal exposure and breastfeeding	Pregnancy Discontinue if pregnancy occurs—no information available. Breast-feeding No information available. Absorption from milk unlikely. Caution should be exercised when somatropin containing products are administered to breast-feeding women.
vi. Adverse effects	Growth hormone is generally well tolerated and has an excellent safety record. Local skin reactions may occur at injection sites. Other side effects are rare but may include: headache* (may be recurrent or severe), nausea and/or vomiting*, visual problems*, glucose intolerance (especially in PWS or Turner patients), arthralgia, myalgia. *Consider fundoscopy to exclude benign intracranial hypertension If myositis develops when using Somatrogon a prescription change to daily growth hormone will be required
vii. Monitoring Requirements	When used in children, monitoring will be carried out as follows by the Paediatrics department: ❑ 4 - 6 monthly monitoring will include plotted growth measurements ❑ Annual monitoring will include IGF1, TFTs and bone age As per NICE guidance, treatment with somatropin should be discontinued by the paediatrician if any of the following apply: ❑ growth velocity increases less than 50% from baseline in the first year of treatment ❑ final height is approached and growth velocity is less than 2 cm total growth in 1 year

	❑ there are insurmountable problems with adherence ❑ final height is attained. Somatrogon: Annual IGF1 levels need to be checked 4 days after the last dose of somatrogon. As per NICE guidance: When used in **adults** the QoL status of people who are given GH treatment should be re-assessed 9 months after the initiation of therapy. GH treatment should be discontinued for those people who demonstrate QoL improvement of less than 7 points in QoL-AGHDA score. Adult patients with GH deficiency are typically commenced on somatropin 200-300 micrograms daily. IGF-1 levels are assessed at one month and dose titrated aiming for a mid-range IGF-1 level. Further IGF-1 check 1 month after each dose change. Annual IGF-1 check is adequate once stable dose is reached.
viii. Clinically relevant drug interactions	Insulin doses may need to be adjusted.
ix. Contraindications	• Patients with any evidence of tumour activity. • In critically ill patients (for example, after complications following open heart or abdominal surgery, multiple trauma, acute respiratory failure or similar conditions). • In patients with known hypersensitivity to growth hormone or to any of the excipients. • In patients with tumours, anti-tumour therapy must be completed before starting GH therapy. • Children with closed epiphyses • During pregnancy and lactation.
x. Additional information	Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed.
xi. Supply of ancillary equipment	All consumables are provided free of charge from the company when growth hormone is initiated. Ongoing supplies of needles and sharps box to be prescribed on a repeat prescription as directed by specialist team.
xii. Supply, storage and reconstitution instructions	Somatropin and Somatrogon should be stored in a refrigerator between 2 and 8ºC out of the reach of children. Ensure patient able to access supply in a timely fashion to avoid unintended treatment gaps. Bi-monthly prescriptions may be considered.
xiii. To be read in conjunction with the following documents	• NHSE policy- Responsibility for prescribing between Primary & Secondary/Tertiary Care • Product SPC
xiv. Prepared by **Reviewed by**	J Vanes, Directorate Lead Pharmacist Women's & Children's P King, Consultant Physician The Derbyshire Medicines Management Shared Care & Guidelines Group Dr Tinklin, Consultant Paediatrician, Derby Hospitals NHS Foundation Trust Lisa Hill Paediatric Endocrine Nurse Specialist UHDB Dr Roger Stanworth, Consultant Physician UHDB

Sample Transfer Letter

Hospital No: «HOSPITAL_NUMBER»
NHS No: «NHS_NUMBER»

{Insert date}
PRIVATE & CONFIDENTIAL
«GP_TITLE» «GP_INITIALS» «GP_SURNAME»
«GP_ADDRESS_1»
«GP_ADDRESS_2»
«GP_ADDRESS_3»
«GP_POSTCODE»

DERBYSHIRE JAPC SHARED CARE AGREEMENT LETTER
Dear «GP_TITLE» «GP_SURNAME»

«FORENAME_1» «SURNAME» «DATE_OF_BIRTH»
«CURRENT_ADDRESS_1» «CURRENT_ADDRESS_2» «CURRENT_ADDRESS_3»
«CURRENT_ADDRESS_4» «CURRENT_POSTCODE»

Your patient was seen on ***{Insert date}*** with a diagnosis of ***{Insert diagnosis}***. I have initiated the following medication ***{Insert drug name}*** and am writing to ask you to participate in the shared care for this patient.

This medication has been accepted as suitable for shared care by the Derbyshire Joint Area Prescribing Committee (JAPC). I agree to the secondary care responsibilities set out in the shared care agreement for this medication (available from www.derbyshiremedicinesmanagement.nhs.uk/clinical_guidelines/shared_care_guidelines). I am therefore requesting your agreement to share the care of this patient. Where preliminary tests are set out in the agreement I have carried these out and results are below.

Dose Regimen	Date ***{Insert medicine name}*** started	Date for GP to start prescribing ***{Insert medicine name}*** from
The baseline test results are (if applicable): **See overleaf for initiation criteria.**		

I can confirm that the following has happened with regard to this treatment:

	Specialist to complete
The patient has been initiated on this therapy and has been on an optimised dose for the following period of time:	
Baseline investigation and monitoring as set out in the shared care documents have been completed and were satisfactory	*Yes / No*
The condition being treated has a predictable course of progression and the patient can be suitably maintained by primary care	*Yes / No*
The risks and benefits of treatment have been explained to the patient	*Yes / No*
The roles of the specialist/specialist team/ Primary Care Prescriber / Patient and pharmacist have been explained and agreed	*Yes / No*
The patient has agreed to this shared care arrangement, understands the need for ongoing monitoring, and has agreed to attend all necessary appointments	*Yes / No*
I have enclosed a copy of the shared care protocol which covers this treatment/the SCP can be found here (insert electronic/ web link)	*Yes / No*
I have included with the letter copies of the information the patient has received	*Yes / No*
I have provided the patient with sufficient medication to last until	
I have arranged a follow up with this patient in the following timescale	

If you do **NOT** wish to participate in shared care for this patient, usually under clinical grounds, please complete the attached form.

Yours sincerely
{Consultant name}

GP RESPONSE TO SHARED CARE (only complete & send if **NOT** participating in shared care*)

* For completeness please record medication on GP clinical system as per guidance- 'Recording medicines prescribed and issued by other Healthcare Providers'

Shared care is produced by GPs and specialists knowledgeable in the field of that drug usage. The shared care has been approved by the JAPC. This allows a more convenient service to the patient and cost effective use of NHS resources.

Patient:	NHS No:
Consultant:	Medicine requested for shared care:

I will **NOT** be undertaking the GP responsibilities as described in the agreed shared care guideline. My clinical reasons for declining shared care for this patient are listed in the box below:

		Tick which apply
1.	**The prescriber does not feel clinically confident in managing this individual patient's condition, and there is a sound clinical basis for refusing to accept shared care** As the patients primary care prescriber I do not feel clinically confident to manage this patient's condition because *[insert reason]*. I have consulted with other primary care prescribers in my practice who support my decision. This is not an issue which would be resolved through adequate and appropriate training of prescribers within my practice. **I have discussed my decision with the patient and request that prescribing for this individual remain with you as the specialist, due to the sound clinical basis given above.**	
2.	**The medicine or condition does not fall within the criteria defining suitability for inclusion in a shared care arrangement** As the medicine requested to be prescribed is not included on the national list of shared care drugs as identified by RMOC or is not a locally agreed shared care medicine I am unable to accept clinical responsibility for prescribing this medication at this time. **Until this medicine is identified either nationally or locally as requiring shared care the responsibility for providing this patient with their medication remains with you**	
3.	**A minimum duration of supply by the initiating clinician** As the patient has not had the minimum supply of medication to be provided by the initiating specialist I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***Until the patient has had the appropriate length of supply the responsibility for providing the patient with their medication remains with you.***	
4.	**Initiation and optimisation by the initiating specialist** As the patient has not been optimised on this medication I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***Until the patient is optimised on this medication the responsibility for providing the patient with their medication remains with you.***	
5.	**Shared Care Protocol not received** As legal responsibility for clinical care lies with the clinician who signs the prescription, I need to ensure that I am in possession of sufficient clinical information for me to be confident to prescribe this treatment for my patient and it is clear where each of our responsibilities lie to ensure the patient is safely managed. For this reason I am unable to take clinical responsibility for prescribing this medication at this time, therefore would you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***Until I receive the appropriate SCP, responsibility for providing the patient with their medication remains with you.***	

6.	**Other (Primary Care Prescriber to complete if there are other reasons why shared care cannot be accepted)**	

Yours sincerely

{GP name}
{Surgery}

Please send a copy of this response to the specialist/consultant requesting shared care