DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE
SHARED CARE AGREEMENT

Synthetic Human Growth Hormone
(SOMATROPIN)

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

<table>
<thead>
<tr>
<th>GP responsibilities</th>
<th>Consultant/specialist responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Reply to the request for shared care as soon as practicable.</td>
<td>1. Selection of patients suitable for treatment</td>
</tr>
<tr>
<td>2. Prescribe growth hormone by brand and at the dose recommended by the specialist</td>
<td>2. Discuss benefits and side effects of treatment with the patient and parent/carer</td>
</tr>
<tr>
<td>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.</td>
<td>3. Recommend starting dose, brand of drug and advise on subsequent dose changes</td>
</tr>
<tr>
<td>4. Report any adverse effects to the referring specialist and the MHRA yellow card scheme.</td>
<td>4. Ensure the parent/carer understands when and how to give the medication</td>
</tr>
<tr>
<td>5. Stop treatment on advice of specialist.</td>
<td>5. Ask the GP whether he or she is willing to participate in shared care.</td>
</tr>
</tbody>
</table>

   | Patient responsibilities                                                             |                                                                                  |
   |-------------------------------------------------------------------------------------|                                                                                  |
   | • Report any adverse effects to the specialist or GP whilst taking somatropin       |                                                                                  |
   | • Share any concerns in relation to treatment with somatropin                       |                                                                                  |
   | • To administer somatropin 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, Derby Children's Hospital – 01332 786824
   Dr Denvir, Dr Randell and Dr Sachdev, Consultant Paediatric Endocrinologists, Nottingham University Hospitals

   **Paediatric Endocrine Nurse specialist**
   Lisa Hill – 07471 140587

   **Adults**
   Consultants in Endocrinology
   Dr Roger Stanworth – 01332 783283
   Dr Paru King – 01332 783284
   Dr Iskandar Idris – 01332 783283
   Dr Suma Sugunendran – 01332 783286
   Dr Hisham Ali – 01332 783284
   Dr David Hughes – 01332 787696
   Dr Supreeth Rudrappa - 01332 783283
   Dr Luckni Sellahewa – 01332 783283
## 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](#)

### Adults
- NICE TA 64 [Human growth hormone in adults with growth hormone deficiency](#)

### 4. CLINICAL INFORMATION

#### i. Prescribed indications
- 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
- 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.
- Short Stature Homeobox-containing gene (SHOX) deficiency

#### 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 Zomacton® which is unlicensed for use in chronic renal insufficiency and SGA and Nutropin Ad® which is unlicensed for use in SGA.
- Genotropin® and Omnitrope® are also licensed for use in Prader-Willi syndrome.
- Humatrope® is the only product licensed for use in SHOX deficiency.

#### iii. Dose & Route of administration
- **As per NICE guidance:**
  - Treatment with a somatropin 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.
  - **Gonadal dysgenesis (Turner syndrome)**
    - 45-50 micrograms/kg daily or 1.4mg/m² daily
  - **Growth hormone deficiency in children**
    - 23-39 micrograms/kg daily or 0.7-1mg/m² 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/m² daily
  - **Prader-Willi syndrome**
    - 35 micrograms/kg daily or 1mg/m² (maximum 2.7mg daily)
  - **Chronic renal insufficiency in children before puberty**
    - 45-50 micrograms/kg daily or 1.4mg/m² daily
  - **Adult growth hormone deficiency**
    - 150-300 micrograms daily gradually increasing to 1mg daily
  - **SHOX deficiency in children**
    - 45-50 microgram/kg of body weight per day
<table>
<thead>
<tr>
<th>iv. Duration of treatment</th>
<th>Indefinite or as per monitoring requirements below</th>
</tr>
</thead>
<tbody>
<tr>
<td>v. Adverse effects</td>
<td>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’s patients), arthralgia, myalgia. *Consider fundoscopy to exclude benign intracranial hypertension</td>
</tr>
<tr>
<td>vi. Monitoring Requirements</td>
<td>When used in children, monitoring will be carried out as follows by the Paediatrics department: 4 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. As per NICE guidance: When used in <strong>adults</strong> 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 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.</td>
</tr>
<tr>
<td>vii. Clinically relevant drug interactions</td>
<td>Insulin doses may need to be adjusted.</td>
</tr>
<tr>
<td>viii. Contraindications</td>
<td>- 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.</td>
</tr>
<tr>
<td>ix. Supply of ancillary equipment</td>
<td>All consumables are provided free of charge from the company when growth hormone is initiated.</td>
</tr>
<tr>
<td>x. Supply, storage and reconstitution instructions</td>
<td>Somatropin should be stored in a refrigerator between 2 and 8°C out of the reach of children.</td>
</tr>
</tbody>
</table>
| xi. Prepared by | *Paediatrics*  
J Vanes, Directorate Lead Pharmacist Women’s & Children’s  
Adults  
P King, Consultant Physician  
Dr Tinklin, Consultant Paediatrician, Derby Hospitals NHS Foundation Trust  
Dr Roger Stanworth, Consultant Physician, Derby Hospitals NHS Foundation Trust |
| Reviewed by |  
The Derbyshire Medicines Management Shared Care & Guidelines Group  
Dr Tinklin, Consultant Paediatrician, Derby Hospitals NHS Foundation Trust  
Dr Roger Stanworth, Consultant Physician, Derby Hospitals NHS Foundation Trust |

This does not replace the SPC, which should be read in conjunction with it  
First Produced: July 2010  
Date Updated: September 2018  
Review Date: August 2020
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.

<table>
<thead>
<tr>
<th>Dose Regimen</th>
<th>Date {Insert medicine name} started</th>
<th>Date for GP to start prescribing {Insert medicine name} from</th>
</tr>
</thead>
</table>

The baseline test results are (if applicable):
See overleaf for initiation criteria.

I confirm I have explained to the patient: the risks and benefits of treatment, the baseline tests conducted the need for monitoring, how monitoring will be arranged, and the roles of the consultant / nurse specialist, GP and the patient in shared care. I confirm the patient has understood and is satisfied with this shared care arrangement at this time.

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)

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.

<table>
<thead>
<tr>
<th>Patient:</th>
<th>NHS No:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultant:</td>
<td>Medicine requested for shared care:</td>
</tr>
</tbody>
</table>

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:

Yours sincerely

{GP name}
{Surgery}

Please send a copy of this response to:

1. The specialist/consultant requesting shared care
2. AN ANONYMISED COPY OF THIS FORM ONLY to the Medicines Management Clinical Effectiveness Team, 1st Floor East Point, Cardinal Square, 10 Nottingham Road, Derby, DE1 3QT or E-MAIL: sderccg.derbyshiremedicinesmanagement@nhs.net

(Sending a copy of this form to the Clinical Effectiveness Team will help to identify any inappropriate requests for shared care e.g. indication not covered, hospital monitoring requirements not fulfilled. It will also help to inform the CCG prescribing group of the reasons shared care is not being undertaken allowing for changes to be made in future updates to improve patient care).