SHARED CARE AGREEMENT: GROWTH HORMONE (SOMATROPIN) IN CHILDREN WITH GROWTH DISTURBANCE

NHS GREATER GLASGOW AND CLYDE

NB: This document should be read in conjunction with the current Summary of Product Characteristics (SPC)

DRUG AND INDICATION:

Generic drug name:	Somatropin (recombinant human growth hormone, r-hGH)
Formulations:	Injection (for subcutaneous or intramuscular injection) available as: Genotropin® Humatrope® Norditropin® NutropinAq® Omnitrope® Saizen® Zomacton® Choice of formulation will be in accordance with local and national guidance.
Intended indication:	1. Growth disturbance in children with growth hormone insufficiency/deficiency (GHD) causing short stature: • Idiopathic isolated GHD • Congenital hypopituitarism e.g. anomalies of the pituitary gland such as septo-optic dysplasia. • Acquired hypopituitarism e.g. craniopharyngioma, post cranial irradiation, neuro-surgery or traumatic brain injury 2. Growth disturbance in girls with Turner Syndrome (confirmed by chromosome analysis). 3. Growth disturbance in children with chronic renal failure (CRF). 4. Improvement in growth and body composition in children with Prader-Willi Syndrome (confirmed by chromosome analysis). 5. Growth disturbance in children born Small for Gestational Age (SGA): • Growth disturbance (current height SDS <-2.5 and parental adjusted height SDS <-1) in short children born SGA who fail to show catch up growth by 4 years. 6. Growth disturbance associated with SHOX deficiency (confirmed by DNA analysis). **NICE Technology Appraisal Guidance 188 May 2010,** **British Society for Paediatric Endocrinology and Diabetes Shared Care Guidelines: Paediatric use of Recombinant human Growth Hormone (r-hGH, Somatropin)**
Status of medicine or treatment:	**Licensed**

RESPONSIBILITIES OF ACUTE CARE/SPECIALIST SERVICE (CONSULTANT/ SPECIALIST NURSE):

To undertake necessary testing to confirm a diagnosis that requires r-hGH treatment, as indicated by NICE guidance.
To provide GP with written information regarding the diagnosis and indication for r-hGH therapy along with dosage and preparation to be used.

To supervise training of patients and families with r-hGH injections, liaise with GP about local arrangements necessary for instigation of therapy and identify any possible barriers to treatment.
To monitor patient's growth, pubertal development, assessment of any other ongoing or evolving endocrinopathy and general condition at 3-6 monthly intervals following instigation of therapy and to advise about dose and/or preparation changes.
To ensure strict adherence to published NICE guidance for initial prescription of r-hGH and monitor ongoing r-hGH therapy.
To supervise the timing for cessation of treatment at final height, reassessment and transition to adult endocrine care where necessary
Monitor endocrine status, particularly thyroid function
Monitor for possible side-effects of treatment
Recommend dose adjustments
Determine frequency of clinic visits
Inform GP of patient's progress, any dose adjustments or termination of therapy

RESPONSIBILITIES OF PRIMARY CARE (GENERAL PRACTITIONER):

Prescribe recommended product and dose as per specialist communication. No regular monitoring required in primary care. Secondary care is responsible for monitoring efficacy and adverse effects. Primary care to advise if any concerns over compliance e.g. frequency of prescription requests

RESPONSIBILITIES OF PATIENT/ CARER:

To ensure they have clear understanding of the prescribed treatment.
To administer the r-hGH as directed by the supervising Consultant; attend clinic reviews as requested.
To share any concerns in relation to treatment with the supervising Consultant and/or GP.
To report any adverse effects to the supervising Consultant and/or GP whilst taking r-hGH

ADDITIONAL RESPONSIBILITIES:

CAUTIONS:

Diabetes mellitus (adjustment of antidiabetic therapy may be necessary), papilloedema (see under Side-effects), relative deficiencies of other pituitary hormones (notably hypothyroidism—manufacturers recommend periodic thyroid function tests but limited evidence of clinical value), history of malignant disease, disorders of the epiphysis of the hip (monitor for limping), resolved intracranial hypertension (monitor closely), initiation of treatment close to puberty not recommended in child born small for corrected gestational age; Silver-Russell syndrome; rotate subcutaneous injection sites to prevent lipoatrophy
(Reference: British National Formulary)

CONTRAINDICATIONS:

Evidence of tumour activity (complete antitumour therapy and ensure intracranial lesions inactive before starting); not to be used after renal transplantation or for growth promotion in children with closed epiphyses (or near closure in Prader-Willi syndrome); severe obesity or severe respiratory syndrome in Prader-Willi syndrome

(Reference: British National Formulary)

TYPICAL DOSAGE REGIMENS:

The choice of product should be made on an individual basis after informed discussion between the responsible clinician and the patient and/or their carer about the advantages and disadvantages of the products available, taking into consideration therapeutic need and the likelihood of adherence to treatment (NICE TA188, May 2010)

Route of administration:	Subcutaneous
Recommended starting dose:	Dependent on indication (usual maintenance doses): Growth Hormone Deficiency 25-40microgram/kg/day (0.7-1mg/ m^2/day) Turner Syndrome 45-50microgram/kg/day (1.4mg/ m^2/day) Chronic Renal Failure 45-50microgram/kg/day (1.4mg/ m^2/day) Prader-Willi Syndrome 35microgram/kg/day (1mg/ m^2/day) Small for gestational age 35microgram/kg/day (1mg/ m^2/day) SHOX deficiency 45-50microgram/kg/day (1.4mg/ m^2/day)
Titration of dose:	According to weight/response(height velocity/IGF-1 level)
Maximum dose:	70microgram/kg/day (or 1.4mg/m^2/day)
Adjunctive treatment regimen:	
Conditions requiring dose adjustment:	
Usual response time:	
Duration of treatment	Until final height achieved and then re-evaluated for adult GH therapy (where appropriate)

SIGNIFICANT DRUG INTERACTIONS:

- Effect may be reduced by use of corticosteroids
- Higher doses of somatropin may be required if concomitant administration of oestrogens

UNDESIRABLE EFFECTS:

Headache, funduscopy for papilloedema recommended if severe or recurrent headache, visual problems, nausea and vomiting occur—if papilloedema confirmed consider benign intracranial hypertension (rare cases reported); fluid retention (peripheral oedema), arthralgia, myalgia, carpal tunnel syndrome, paraesthesia, antibody formation, hypothyroidism, insulin resistance, hyperglycaemia, hypoglycaemia, reactions at injection site; leukaemia in children with growth hormone deficiency also reported

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ADR details (where possible indicate if common, rare or serious)	Management of ADR
Headache	▪ Cessation of GH therapy and re- introduce at lower dose
Slipped Femoral Epiphysis	▪ Orthopaedic review
	▪
	▪

BASELINE INVESTIGATIONS:

Where appropriate all patients should have their GH axis evaluated , together with pituitary imaging and assessment of other endocrinopathies. (note: PWS, Turner's syndrome, Chronic Renal Failure, SGA and SHOX this may not be required).

MONITORING (PRIMARY CARE):

- The following monitoring is to be undertaken in Primary Care

Monitoring Parameters	Frequency	Laboratory results	Action to be taken
Nil			

MONITORING (ACUTE SECTOR):

- The following monitoring is to be undertaken in Acute Care

Monitoring Parameters	Frequency	Laboratory results	Action to be taken
IGF-1	6-12 monthly		Dose titration
Growth	4-6 monthly		Dose titration
Evolving endocrinopathy	6-12 monthly		

PHARMACEUTICAL ASPECTS:

The choice of product should be made on an individual basis after informed discussion between the responsible clinician and the patient and/or their carer about the advantages and disadvantages of the products available, taking into consideration therapeutic need and the likelihood of adherence to treatment (NICE TA188, May 2010).
The appropriate device for the somatotropin choosen by the parent/carer/patient will be provided by acute care (and any replacement).

COST:

Cost dependant on product however NHS indicative price (as per BNF) is in the order of £17-£40/mg. Annual cost in the order of £8,000 (based on NHS indicative cost of pre-filled pen and 5-7 year old, 20kg child).

INFORMATION FOR COMMUNITY PHARMACIST:

Injection devices will be supplied by acute care.

ACUTE CARE/SPECIALIST SERVICE CONTACT INFORMATION:

Name	Designation	Acute Site	Department phone number
Heather Kyle Rosin Boyle	Endocrine Nurse Specialists	Royal Hospital for Children	01414524911 (voicemail) 07904881485
Dr Guftar Shaikh	Consultant Endocrinologist	Royal Hospital for Children	01414516548 (secretary)
Prof. Faisal Ahmed	Consultant Endocrinologist	Royal Hospital for Children	01414516548 (secretary)
Dr Avril Mason	Consultant Endocrinologist	Royal Hospital for Children	01414516548 (secretary)
Dr Jarod Wong	Consultant Endocrinologist	Royal Hospital for Children	01414516548 (secretary)
Dr Andreas Kyriakou	Senior Clinical Fellow in Endocrinology	Royal Hospital for Children	01414516548 (secretary)

SUPPORTING DOCUMENTATION:

Product-specific patient information leaflets (PIL) are provided.

BSPED Shared Care Protocol

SharedcareGH-BSPED.pdf

NICE

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