SHARED CARE AGREEMENT: GROWTH HORMONE IN CHILDREN AND YOUNG ADULTS ≤ 25 years old 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:	Recombinant human growth hormone, r-hGH – Daily injections or weekly injections
Formulations:	Subcutaneous injection available as: **Daily injections (somatropin):** • Genotropin® • Norditropin® • Omnitrope® • Saizen® **Weekly Injections (somatrogon/somapacitan):** • Ngenla® • Sogroya® Choice of formulation will be in accordance with local and national guidance.
Intended indication:	**Daily injections (somatropin):** 1. Growth disturbance in children with growth hormone insufficiency/deficiency (GHD) causing short stature. 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 (current height SDS <-2.5 and parental adjusted height SDS <-1)in children born Small for Gestational Age (SGA) who fail to show catch up growth by 4 years. 6. Growth disturbance associated with SHOX deficiency (confirmed by DNA analysis). 7. Growth disturbance associated with Noonan syndrome **Weekly Injections (somatrogon/somapacitan):** 1. Growth hormone deficiency in children and adolescents from 3 years of age.
Status of medicine or treatment:	Licensed. However, not all products are licensed for every indication. Refer to each individual product's Summary of Product Characteristics for additional information.

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.
- Paediatric endocrinology services will be responsible for patients up to and including the age of 25 years of age.
- 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:

None

CAUTIONS:

- Diabetes mellitus (adjustment of antidiabetic therapy may be necessary).
- Glucose intolerance or risk factors for diabetes (additional monitoring 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).
- Hypoadrenalism (initiation or adjustment of glucocorticoid replacement therapy may be necessary).
- History of malignant disease or benign tumour.
- Disorders of the epiphysis of the hip (monitor for limping).

CONTRAINDICATIONS:

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

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.

Route of administration:	Subcutaneous
Recommended starting dose:	Dependent on indication: **Daily injection (somatropin):** • Growth Hormone Deficiency: 23-39microgram/kg/day (0.7-1mg/ m^2/day) • Turner Syndrome: 45-50microgram/kg/day (1.4mg/ m^2/day) • Chronic Renal Insufficiency (renal function decreased to less than 50%): 45-50microgram/kg/day (1.4mg/ m^2/day) • Prader-Willi Syndrome: 35microgram/kg/day (0.5-1mg/ m^2/day) maximum 2.7mg/day • Small for gestational age (≥4 years old): 35microgram/kg/day (1mg/ m^2/day) • SHOX deficiency: 45-50microgram/kg/day (1.4mg/ m^2/day) • Noonan Syndrome: 30-60microgram/kg/day **Weekly injection (somatrogon/somapacitan):** • Growth Hormone Deficiency in children and adolescents from 3 years of age: **Ngenla**® 0.66mg/kg/week • Growth Hormone Deficiency in children and adolescents from 3 years of age : **Sogroya**® 0.16mg/kg/week
Titration of dose:	According to weight/response(height velocity/IGF-1 level)
Maximum dose (Daily injection):	70microgram/kg/day (or 1.4mg/m^2/day) Note - Maximum dose preferred as m^2/day in obese individuals
Maximum dose (Weekly injection):	To be determined by responsible Endocrine Consultant
Adjunctive treatment regimen:	N/A
Conditions requiring dose adjustment:	To be determined by responsible Endocrine Consultant
Usual response time:	Variable
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 growth hormone may be required if concomitant administration of oestrogens
- Treatment with growth hormone may decrease insulin sensitivity. The dose of insulin and/or hypoglycaemic medicinal products may require adjustment when therapy is initiated.

UNDESIRABLE EFFECTS:

ADR details (where possible indicate if common, rare or serious)	Management of ADR
Headache (common)	Cessation of GH therapy and re- introduce at lower dose
Benign intracranial hypertension (uncommon)	A severe and persistent headache, visual problems, nausea/vomiting should be reported immediately to the Specialist. Consider fundoscopy for papilloedema.
Lipoatrophy (common)	Ensure rotation of injection site
Slipped Femoral Epiphysis (rare)	Orthopaedic review

Fluid retention (peripheral oedema), arthralgia, myalgia, carpal tunnel syndrome, paraesthesia, antibody formation, hypothyroidism, insulin resistance, hyperglycaemia, hypoglycaemia, pancreatitis, reactions at injection site; leukaemia in children with growth hormone deficiency also reported.

The above list should not be considered exhaustive. For further documented ADRS, and details of likelihood etc, see Summary of Product Characteristics or BNF.

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):

No monitoring is to be undertaken in Primary Care

MONITORING (ACUTE SECTOR):

- The following monitoring is to be undertaken in Acute Care

Monitoring Parameters	Frequency	Action to be taken
Insulin-like Growth Factor-1 (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, likelihood of adherence to treatment, product license and cost.
The appropriate device for the product chosen by the parent/carer/patient will be provided by acute care (and any replacement).

See individual product Summary of Product Characteristics for storage advice and in use expiries. Generally all growth preparations require refrigeration (2 – 8°C) prior to and during use.

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
Roisin Boyle Jennifer Sanderson Nicola Hanel	Endocrine Nurse Specialists	Royal Hospital for Children	07904881485/ggc.rhsc.endocrine@nhs.scot
Dr Guftar Shaikh	Consultant Endocrinologist	Royal Hospital for Children	01414516548 (secretary)
Prof. Faisal Ahmed	Consultant Endocrinologist	Royal Hospital for Children	01414516548 (secretary)
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Dr Ching Chen	Consultant Endocrinologist	Royal Hospital for Children	01414516548 (secretary)
Dr Angela Lucas-Herald	Consultant Endocrinologist	Royal Hospital for Children	0141 451 6540 (secretary)

SUPPORTING DOCUMENTATION:

Product-specific Summary of Product Characteristics and Patient Information Leaflets (PIL) available from https://www.medicines.org.uk/.

BSPED, Paediatric use of Recombinant human Growth Hormone (r-hGH, Somatropin), Shared Care Guideline 2012

NICE - Human growth hormone (somatropin) for the treatment of growth failure in children. Issued: May 2010

British Society for Paediatric Endocrinology and Diabetes Shared Care Guidelines: Shared care guidelines for paediatric use of daily and long-acting recombinant human growth hormone. 2023.

British National Formulary for Children