SHARED CARE AGREEMENT

Name of medicine Somatropin (synthetic human growth hormone)

Indication Adult Hypopituitarism

Version: **2.0** Approval date: **September 2025** Review date: **September 2028**

The Shared Care Agreement (SCA) is intended to facilitate the accessibility and safe prescribing of complex treatments across the secondary/primary care interface. It does not contain all of the relevant product information, which should be sought using the current British National Formulary and manufacturer's Summary of Product Characteristics. The SCA must be used in conjunction with the NHS Lothian Procedure for the Shared Care of Medicines, available here.

Roles and responsibilities

Listed below are specific responsibilities that are additional to those included in the NHS Lothian Policy and Procedures for Shared Care. Please refer to the policy for core roles and responsibilities that apply to all Shared Care Agreements.

Consultant/Nurse Specialists

- Diagnosis of growth hormone deficiency in patients with hypopituitarism who remain symptomatic despite conventional replacement therapy and who would consider self-administration of growth hormone.
- Assessing need for somatropin and recommending treatment regimen.
- Ensure that the patient/carer has adequate instruction on the administration of somatropin to safely administer at home.
- Liaising with the GP to share care and assure appropriate administration of the drug via endocrine nurses teaching the patients self-injection techniques
- Adjusting dosage and communicating information on dose changes to the patient's GP.
- Assessing and monitoring the patient's response to treatment.
- Provide information to the GP on brand of somatropin used, dose, frequency and any other drugs the patient is taking.
- Consultants will undertake follow-up in the Endocrine clinic, initially at 6 months and annually thereafter. If requested by the GP, we will respond to any concerns raised by the patient between visits.

General Practitioner

- Prescribing the growth hormone by brand and the administration devices (if required), as advised by the hospital consultant and ensure that the patient stays on the same preparation.
- Promoting compliance.
- Reporting any suspected adverse effects to the specialist team.

Patient, Relatives, Carers

- Report any adverse effects to GP or consultant.

Support and Advice for the GP

In the first instance, please contact the patient's endocrinologist at the Western General Hospital (0131 537 1000), Royal Infirmary of Edinburgh (0131 242 1000) or St John's Hospital 01506 523 000

For Metabolic Unit Nurses contact 0131 537 2473

Urgent problems

Please contact the on-call Endocrinology Registrar or the on-call Endocrinology Consultant, via the Western General Hospital or Royal Infirmary of Edinburgh switchboard.

Key Information on the Medicine

Please refer to the current edition of the British national Formulary (BNF), available at www.bnf.org, and Summary of Product Characteristics (SPC), available at www.medicines.org.uk for detailed product and prescribing information and specific guidance.

Background to disease and use of drug for the given indication

Somatropin (Recombinant Human Growth Hormone) is recommended as a treatment option for adults under the following conditions:

- Children with GHD will be re-tested by their paediatric endocrinologist once adult height is achieved. Those with ongoing severe growth hormone deficiency will be offered ongoing growth hormone replacement till the age of 25 to promote peak bone mineral density (See SPEG position statement below). Thereafter, treatment decisions follow the standard adult pathway as described below.
- Severe growth hormone deficiency in adults.
- Patients with hypopituitarism (most commonly due to pituitary tumours) receive replacement with hydrocortisone, levothyroxine, sex steroids and sometimes DDAVP. However, despite careful titration of these therapies, some hypopituitary patients have residual problems, including lethargy, reduced muscle mass, central obesity, and an increased risk of cardiovascular mortality.
- There is evidence that growth hormone replacement produces beneficial effects on muscle mass and strength, body fat distribution, blood lipid levels, insulin sensitivity, bone mineral density, and cardiac output. Most importantly, some patients experience a dramatic improvement in well-being and quality of life. This response is hard to predict and varies markedly between patients. No data are available to establish whether growth hormone prolongs life, but in this rare group of patients (fewer than 0.01% prevalence) a randomised controlled outcome trial is unlikely ever to be performed. The view of NHS Lothian Endocrinologists is that it should be offered to patients who derive symptomatic benefit, but not to all hypopituitary adults.

The following NICE Technology Appraisal and Position Statement provides guidance in prescribing Growth Hormone in Adults.

NICE TA 64 Human growth hormone (somatropin) in adults with growth hormone deficiency
https://www.nice.org.uk/guidance/ta64

SPEG position statement on GH assessment and treatment during transition
NSD610-016.10-SPEG-Position-Statement-on-the-investigation-treatment-of-Growth-Hormone-Deficiency-in-Transition.pdf

Supply of Growth Hormone in Scotland is initiated via Secondary Care, however, the majority of patients are supplied in Scotland via Primary Care, through shared care arrangements.

The additional costs of growth hormone therapy in adults have been approved by the Lothian Formulary Committee as an Additional List Drug.

Recombinant growth hormone has been licensed for use in adults since 1995.

This guidance is for new patients in adult patient cohorts.

Indication

Patients with documented hypopituitarism are eligible for consideration of Growth Hormone replacement therapy if they are:

- aged >18 years
- are symptomatic despite adequate replacement of all other hormonal deficiencies, eg with lethargy, reduced muscle power, associated with central obesity OR are under 25 and require ongoing treatment to promote peak bone mineral density.
- would consider daily self-injection.
- have no contra-indications, including diabetes mellitus, concurrent malignant disease, cardiac failure, are at risk of pregnancy.
- have a score of >11 on a disease-specific Adult Growth Hormone Deficiency Assessment scale.
- have confirmed growth hormone deficiency on dynamic testing.

Dosage and Administration

- Growth hormone replacement is administered as a daily subcutaneous injection at bed-time. Usually, the drug is supplied in disposable pens containing two cartridges (of powder and diluent) which are mixed inside the pen pre-injection. Alternative injections are available as single dose premixed injection packs. Norditropin®, and Omnitrope are on the East Region Formulary.
- Genotropin is no longer on the formulary due to intermittent supply problems, patient's stabilised on this should continue on Genotropin, however, new patients should be initiated on formulary choices.

- Endocrine nurses will supervise a graded incremental increase in dose during the first 2 months. Doses required to normalise IGF1 vary between 0.2 mg and 0.6 mg per day. These doses are lower than the licensed dose regime of between 0.04 and 0.08 mg/kg body weight/ week.

    - *Growth hormone deficient adult patients:* In patients who continue growth hormone therapy after childhood GHD, the recommended dose to restart is 0.2 – 0.5 mg per day; the dose will be determined by the endocrine team. The dose should be gradually increased or decreased according to individual patient requirements as determined by the IGF-I concentration.

In patients with adult-onset GHD, therapy should start with a low dose, 0.1 – 0.3 mg per day; the dose will be determined by the endocrine team. The dose should be gradually increased according to individual patient requirements as determined by the IGF-I concentration.

Monitoring

No monitoring is required by the GP between hospital visits to the Endocrine Clinic. These patients will be seen on a 3-6 monthly basis initially and correspondence will be sent to the GP following each visit.

Cautions, contraindications

- Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Adverse effects

- Refer to current Summary of Product Characteristics (SPC) for full list: www.medicines.org.uk

Adverse effects include:

- **Lipoatrophy** – site of injection should be varied to avoid lipoatrophy
- **Hypothyroidism** – thyroid function will be monitored at clinic
- **Insulin resistance** – somatropin may produce insulin resistance and this will be monitored at the clinic. Patients who are already diabetic may have increased insulin requirements.
- **Hypertension** – blood pressure will be monitored in clinic.

Drug Interactions

- Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

The presence of this Shared Care Agreement does not compel a primary care prescriber to prescribe if they feel that it is out with the scope of their competencies (as per GMC guidance on safe prescribing) or resources, as ultimate responsibility lies with the prescribing, not the recommending, clinician.

For office use only:

Approved by the General Practice Prescribing Committee (GPPC) on 9th September 2025