**Cardiff & Vale (C&V) UHB Corporate Medicines Management Group (c MMG)**
**SHARED CARE**

| **Protocol No** | **CV 34 SOMATROPIN for ADULT GROWTH DISORDERS** |
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| **General guidance** | It outlines shared care arrangements for adults receiving growth hormone (GH or somatropin) for the treatment of growth disorders. This document should be read in conjunction with the Summary of Product Characteristics that relates to the particular brand of somatropin being prescribed see: http://www.medicines.org.uk/ |
| **1. Licensed indication** | Replacement therapy in adults with pronounced growth hormone deficiency (defined as patients with known hypothalamic pituitary pathology and at least one known deficiency of a pituitary hormone not being prolactin).<br><br>Childhood onset growth hormone insufficiency. |
| **2. Therapeutic use and background** | The estimated prevalence of adult GH deficiency is 1: 10,000 and such patients have abnormal body composition (increased fat mass, reduced muscle bulk, increased waist/hip ratio) and lipid profiles, reduced bone density, reduced muscle strength and vitality, reduced cardiovascular performance and impaired quality of life. These abnormalities can be restored to normal following GH replacement therapy.<br>The commonest cause of adult GH deficiency is the presence and/or treatment of pituitary tumour but rarer cases include other forms of infiltrative or granulomatous hypothalamic-pituitary disease (e.g. sarcoidosis, histiocytosis X), irradiation, pituitary infarction, and idiopathic GH deficiency causing short stature in childhood. Recent evidence indicates that up to 50% of such patients may benefit from GH replacement.<br><br>Diagnosis of GH deficiency is based on the presence of recognisable clinical symptoms of a subnormal GH response (peak <3 micrograms/l) to insulin-induced hypoglycaemia (or other test of GH secretion if IIH is contraindicated) together with a low/low normal IGF-1 level. The initial screening will include clinical assessment, psychological profile (quality of life assessment by the Adult Growth Hormone Deficiency Assessment [AGHDA] questionnaire) and Body Mass Index (BMI) Suitable patients (identified according to NICE TA64 http://guidance.nice.org.uk/TA64/?c=91500) will then be commenced on treatment with somatropin and the dose titrated up to achieve IGF-1 levels in the upper half of the age-related reference range. After 9 months a decision will be made as to whether it is appropriate to continue with long term treatment following discussion between patient, GP and endocrinologist, according to NICE TA64. |
| **3. Contraindications** | Somatropin should not be used<br>1. when there is any evidence of tumour activity (complete anti-tumour therapy and ensure intracranial lesions inactive before starting)<br>2. in patients with Prader-Willi syndrome who are severely obese or have severe respiratory impairment,<br>3. in patients with acute critical illness suffering complications following open heart surgery, abdominal surgery, multiple accidental trauma, acute respiratory failure or similar conditions.<br>Hypersensitivity to somatropin or to any of the excipients. |

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| | *Pregnancy and breastfeeding:* Treatment should be interrupted if pregnancy occurs and should be avoided while breastfeeding. |
| **4. Typical dosage regimen** | Somatropin therapy is started as a low dose which may be gradually increased to normalise IGF-1 levels. The starting dose will be 200micrograms (0.2 mg) daily delivered by self-injection (subcutaneous) in the form of seven daily doses at mid to late evening. Dose titration and assessment of response will be supervised by the endocrine unit over the first 9 months of treatment. |
| **5. Drug interactions** | Somatropin therapy in adulthood is safe and no specific drug interactions have been reported, however diabetic patients may require adjustment of their therapy. |
| **6. Adverse drug reactions**<br><br>**Any serious reaction to an established drug should be reported to the MHRA.** | ***Clinical condition*** / ***Management***<br>Headache. If severe, persistent, recurrent or associated with nausea and vomiting. — Report immediately to the UHW Endocrinology department.<br>Lipoatrophy may occur at site of injection. — This can be avoided by varying the site of administration.<br>Hypothyroidism has been observed with somatropin (rare). — Thyroid function should be monitored in patients with hypopituitarism (see box 8.)<br>Insulin resistance, patients who are already diabetic may have increased insulin requirements. — $HbA_{1C}$ should be monitored in patients with diabetes (see box 8.) and patients advised accordingly<br>Somatropin administration is followed by a transient phase of non-significant hypoglycaemia (approx. 2 hours) then from 2-4 hours onward by a minor increase in blood glucose levels.<br>Signs of fluid retention (e.g. peripheral oedema, stiffness in the extremities, arthralgia, myalgia and paraesthesia) are common when starting somatropin. — Usually mild to moderate and subside spontaneously or with dose reduction.<br>Discuss if persistent or severe paraesthesia present – dose reduction may be necessary to avoid the development of carpal tunnel syndrome<br>Antibody formation is common but seldom clinically relevant. |
| **7. Baseline investigations** | **Undertaken by specialist centre**<br>BMI, BP, $HbA_{1C}$ (in patients with diabetes), thyroid function and IGF-1. |
| **8. Monitoring** | **Undertaken by specialist centre**<br>The hospital specialist will continue to review the patient at six to twelve-monthly intervals with clinical and biochemical assessment including AGHDA questionnaire$HbA_{1C}$ (in patients with diabetes), thyroid function and IGF-1. |
| **9. Pharmaceutical aspects** | There are currently 6 preparations of somatropin available, in many different presentations. The brand of somatropin prescribed in the hospital will be specified and should be continued.<br>Somatropin manufacturers make available suitable disposable syringes and needles and a range of pen injector devices. The latter will usually be distributed via the |

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| | specialist clinic. Storage containers and safety bins are also provided. |
| **10. Specialist centre contact information** | If stopping the medication or needing advice – please contact:<br>the UHW Endocrinology department |
| **11. Criteria for shared care** | Prescribing responsibility will only be transferred when<br>➢ Treatment is for a specified indication.<br>➢ Treatment has been initiated and established by the endocrinologist.<br>➢ The patient's initial reaction to and progress on the drug is satisfactory.<br>➢ The patient's general physical, mental and social circumstances are such that he/she would benefit from shared care arrangements. |
| **12. Responsibilities of Specialist Centre** | ➢ To confirm patient's understanding and consent to treatment.<br>➢ To advise the patient on potential side effects (particularly severe or recurrent headache, nausea and/or vomiting) and the action to be taken should they occur.<br>➢ To initiate treatment with somatropin and provide a minimum of one month's supply.<br>➢ To provide training for patient and ensure they are familiar with how to administer somatropin.<br>➢ To send the GP a Shared Care Request Form when treatment is initiated and invite to participate in the shared care management of the patient.<br>➢ When a GP positive response to Shared care has been received send a letter to GP "handing over" the Shared Care of the patient to the GP.<br>➢ To supply information to GP on brand of somatropin used, dose, frequency and any other drugs patient is taking.<br>➢ To assess and monitor patient's response to treatment, to adjust somatropin dose and to perform the on-going monitoring (as above in box 8.).<br>➢ To inform the GP of dosage schedule, monitoring measurements and progress of treatment after each appointment.<br>➢ To inform the GP if the patient fails to attend an appointment and clearly indicate that the patient is receiving somatropin.<br>➢ Stop the treatment when considered to be no longer appropriate. |
| **13. Responsibilities of patients** | ➢ To attend hospital and GP clinic appointments. Failure to attend will result in the medication being stopped.<br>➢ To report any adverse events to their specialist or GP. |
| **14. Responsibilities of Primary Care** | ➢ Within one week of receipt return the completed Shared Care request form to indicate whether or not willing to undertake Shared Care.<br>➢ To issue ongoing prescriptions for somatropin as per dosage schedule recommended by the specialist and to promote and monitor compliance.<br>➢ To inform the specialist services of severe untoward events or side effects and to report these to the MHRA (using the Yellow Card scheme) as appropriate.<br>➢ To monitor the general health of the patient<br>➢ To act on advice provided by the Consultant if patient does not attend for appropriate monitoring |

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