SA2032 - Somatropin

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Somatropin

Initial application — growth hormone deficiency in children
Applications only from a paediatric endocrinologist or endocrinologist. Approvals valid for 9 months.
Prerequisites(tick boxes where appropriate)

☐ Growth hormone deficiency causing symptomatic hypoglycaemia, or with other significant growth hormone deficient sequelae (e.g. cardiomyopathy, hepatic dysfunction) and diagnosed with GH < 5 mcg/l on at least two random blood samples in the first 2 weeks of life, or from samples during established hypoglycaemia (whole blood glucose < 2 mmol/l using a laboratory device)

or

☐ Height velocity < 25th percentile for age adjusted for bone age/pubertal status if appropriate over 6 or 12 months using the standards of Tanner and Davies (1985)

and

☐ A current bone age is < 14 years (female patients) or < 16 years (male patients)

and

☐ Peak growth hormone value of < 5.0 mcg per litre in response to two different growth hormone stimulation tests. In children who are 5 years or older, GH testing with sex steroid priming is required

and

☐ If the patient has been treated for a malignancy, they should be disease free for at least one year based upon follow-up laboratory and radiological imaging appropriate for the malignancy, unless there are strong medical reasons why this is either not necessary or appropriate

and

☐ Appropriate imaging of the pituitary gland has been obtained

Renewal — growth hormone deficiency in children

Current approval Number (if known):.....

Applications only from a paediatric endocrinologist or endocrinologist. Approvals valid for 12 months.
Prerequisites(tick boxes where appropriate)

☐ A current bone age is 14 years or under (female patients) or 16 years or under (male patients)

and

☐ Height velocity is greater than or equal to 25th percentile for age (adjusted for bone age/pubertal status if appropriate) while on growth hormone treatment, as calculated over six months using the standards of Tanner and Davis (1985)

and

☐ Height velocity is greater than or equal to 2.0 cm per year, as calculated over 6 months

and

☐ No serious adverse effect that the patients specialist considers is likely to be attributable to growth hormone treatment has occurred

and

☐ No malignancy has developed since starting growth hormone

Initial application — Turner syndrome
Applications only from a paediatric endocrinologist or endocrinologist. Approvals valid for 9 months.
Prerequisites(tick boxes where appropriate)

☐ The patient has a post-natal genotype confirming Turner Syndrome

and

☐ Height velocity is < 25th percentile over 6-12 months using the standards of Tanner and Davies (1985)

and

☐ A current bone age is < 14 years

I confirm the above details are correct and that in signing this form I understand I may be audited.

Signed: ..... Date: .....

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Somatropin *- continued*

Renewal — Turner syndrome

Current approval Number (if known):.....

Applications only from a paediatric endocrinologist or endocrinologist. Approvals valid for 12 months.

Prerequisites(tick boxes where appropriate)

- ☐ Height velocity is greater than or equal to 50th percentile for age (while on growth hormone calculated over 6 to 12 months using the Ranke's Turner Syndrome growth velocity charts)

and

- ☐ Height velocity is greater than or equal to 2 cm per year, calculated over six months

and

- ☐ A current bone age is 14 years or under

and

- ☐ No serious adverse effect that the specialist considers is likely to be attributable to growth hormone treatment has occurred

and

- ☐ No malignancy has developed since starting growth hormone

Initial application — short stature without growth hormone deficiency

Applications only from a paediatric endocrinologist or endocrinologist. Approvals valid for 9 months.

Prerequisites(tick boxes where appropriate)

- ☐ The patient's height is more than 3 standard deviations below the mean for age or for bone age if there is marked growth acceleration or delay

and

- ☐ Height velocity is < 25th percentile for age (adjusted for bone age/pubertal status if appropriate), as calculated over 6 to 12 months using the standards of Tanner and Davies(1985)

and

- ☐ A current bone age is < 14 years or under (female patients) or < 16 years (male patients)

and

- ☐ The patient does not have severe chronic disease (including malignancy or recognized severe skeletal dysplasia) and is not receiving medications known to impair height velocity

Renewal — short stature without growth hormone deficiency

Current approval Number (if known):.....

Applications only from a paediatric endocrinologist or endocrinologist. Approvals valid for 12 months.

Prerequisites(tick boxes where appropriate)

- ☐ Height velocity is greater than or equal to 50th percentile (adjusted for bone age/pubertal status if appropriate) as calculated over 6 to 12 months using the standards of Tanner and Davies (1985)

and

- ☐ Height velocity is greater than or equal to 2 cm per year as calculated over six months

and

- ☐ A current bone age is 14 years or under (female patients) or 16 years or under (male patients)

and

- ☐ No serious adverse effect that the patient's specialist considers is likely to be attributable to growth hormone treatment has occurred

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Somatropin *- continued*

Initial application — short stature due to chronic renal insufficiency

Applications only from a paediatric endocrinologist, endocrinologist or renal physician on the recommendation of a paediatric endocrinologist or endocrinologist. Approvals valid for 9 months.

Prerequisites(tick boxes where appropriate)

- ☐ The patient's height is more than 2 standard deviations below the mean

and

- ☐ Height velocity is < 25th percentile (adjusted for bone age/pubertal status if appropriate) as calculated over 6 to 12 months using the standards of Tanner and Davies (1985)

and

- ☐ A current bone age is to 14 years or under (female patients) or to 16 years or under (male patients)

and

- ☐ The patient is metabolically stable, has no evidence of metabolic bone disease and absence of any other severe chronic disease

and

- ☐ The patient is under the supervision of a specialist with expertise in renal medicine

and

- ☐ The patient has a GFR less than or equal to 30 ml/min/1.73m^2 as measured by the Schwartz method (Height(cm)/plasma creatinine (umol/l)) × 40 = corrected GFR (ml/min/1.73m^2) in a child who may or may not be receiving dialysis

or

- ☐ The patient has received a renal transplant and has received < 5mg/ m^2/day of prednisone or equivalent for at least 6 months.

Renewal — short stature due to chronic renal insufficiency

Current approval Number (if known):.....

Applications only from a paediatric endocrinologist, endocrinologist or renal physician on the recommendation of a paediatric endocrinologist or endocrinologist. Approvals valid for 12 months.

Prerequisites(tick boxes where appropriate)

- ☐ Height velocity is greater than or equal to 50th percentile (adjusted for bone age/pubertal status if appropriate) as calculated over 6 to 12 months using the standards of Tanner and Davies (1985)

and

- ☐ Height velocity is greater than or equal to 2 cm per year as calculated over six months

and

- ☐ A current bone age is 14 years or under (female patients) or 16 years or under (male patients)

and

- ☐ No serious adverse effect that the patients specialist considers is likely to be attributable to growth hormone has occurred

and

- ☐ No malignancy has developed after growth hormone therapy was commenced

and

- ☐ The patient has not experienced significant biochemical or metabolic deterioration confirmed by diagnostic results

and

- ☐ The patient has not received renal transplantation since starting growth hormone treatment

and

- ☐ If the patient requires transplantation, growth hormone prescription should cease before transplantation and a new application should be made after transplantation based on the above criteria

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Somatropin *- continued*

Initial application — Prader-Willi syndrome
Applications only from a paediatric endocrinologist or endocrinologist. Approvals valid for 9 months.
Prerequisites(tick boxes where appropriate)

- ☐ The patient has a diagnosis of Prader-Willi syndrome that has been confirmed by genetic testing or clinical scoring criteria

and

- ☐ The patient is aged six months or older

and

- ☐ A current bone age is < 14 years (female patients) or < 16 years (male patients)

and

- ☐ Sleep studies or overnight oximetry have been performed and there is no obstructive sleep disorder requiring treatment, or if an obstructive sleep disorder is found, it has been adequately treated under the care of a paediatric respiratory physician and/or ENT surgeon

and

- ☐ The patient is aged two years or older

and

- ☐ There is no evidence of type II diabetes or uncontrolled obesity defined by BMI that has increased by greater than or equal to 0.5 standard deviations in the preceding 12 months

or

- ☐ The patient is aged between six months and two years and a thorough upper airway assessment is planned to be undertaken prior to treatment commencement and at six to 12 weeks following treatment initiation

Renewal — Prader-Willi syndrome

Current approval Number (if known):.....

Applications only from a paediatric endocrinologist or endocrinologist. Approvals valid for 12 months.
Prerequisites(tick boxes where appropriate)

- ☐ Height velocity is greater than or equal to 50th percentile (adjusted for bone age/pubertal status if appropriate) as calculated over 6 to 12 months using the standards of Tanner and Davies (1985)

and

- ☐ Height velocity is greater than or equal to 2 cm per year as calculated over six months

and

- ☐ A current bone age is 14 years or under (female patients) or 16 years or under (male patients)

and

- ☐ No serious adverse effect that the patient's specialist considers is likely to be attributable to growth hormone treatment has occurred

and

- ☐ No malignancy has developed after growth hormone therapy was commenced

and

- ☐ The patient has not developed type II diabetes or uncontrolled obesity as defined by BMI that has increased by greater than or equal to 0.5 standard deviations in the preceding 12 months

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Somatropin *- continued*

Initial application — adults and adolescents
Applications only from a paediatric endocrinologist or endocrinologist. Approvals valid for 9 months.

Prerequisites(tick boxes where appropriate)

☐ The patient has a medical condition that is known to cause growth hormone deficiency (e.g. surgical removal of the pituitary for treatment of a pituitary tumour)

and

☐ The patient has undergone appropriate treatment of other hormonal deficiencies and psychological illnesses

and

☐ The patient has severe growth hormone deficiency (see notes)

and

☐ The patient's serum IGF-I is more than 1 standard deviation below the mean for age and sex

and

☐ The patient has poor quality of life, as defined by a score of 16 or more using the disease-specific quality of life questionnaire for adult growth hormone deficiency (QoL-AGHDA®)

Note: For the purposes of adults and adolescents, severe growth hormone deficiency is defined as a peak serum growth hormone level of less than or equal to 3 mcg per litre during an adequately performed insulin tolerance test (ITT) or glucagon stimulation test.
Patients with one or more additional anterior pituitary hormone deficiencies and a known structural pituitary lesion only require one test. Patients with isolated growth hormone deficiency require two growth hormone stimulation tests, of which, one should be ITT unless otherwise contraindicated. Where an additional test is required, an arginine provocation test can be used with a peak serum growth hormone level of less than or equal to 0.4 mcg per litre.
The dose of somatropin should be started at 0.2 mg daily and be titrated by 0.1 mg monthly until the serum IGF-I is within 1 standard deviation of the mean normal value for age and sex; and
Dose of somatropin not to exceed 0.7 mg per day for male patients, or 1 mg per day for female patients.
At the commencement of treatment for hypopituitarism, patients must be monitored for any required adjustment in replacement doses of corticosteroid and levothyroxine.

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Somatropin *- continued*

Renewal — adults and adolescents

Current approval Number (if known):.....

Applications only from a paediatric endocrinologist or endocrinologist. Approvals valid for 12 months.

Prerequisites(tick boxes where appropriate)

- ☐ The patient has been treated with somatropin for < 12 months

and

- ☐ There has been an improvement in Quality of Life defined as a reduction of at least 8 points on the Quality of Life Assessment of Growth Hormone Deficiency in Adults (QoL-AGHDA®) score from baseline

and

- ☐ Serum IGF-I levels have been increased within ±1SD of the mean of the normal range for age and sex

and

- ☐ The dose of somatropin has not exceeded 0.7 mg per day for male patients, or 1 mg per day for female patients

or

- ☐ The patient has been treated with somatropin for more than 12 months

and

- ☐ The patient has not had a deterioration in Quality of Life defined as a 6 point or greater increase from their lowest QoL-AGHDA® score on treatment (other than due to obvious external factors such as external stressors)

and

- ☐ Serum IGF-I levels have continued to be maintained within ±1SD of the mean of the normal range for age and sex (other than for obvious external factors)

and

- ☐ The dose of somatropin has not exceeded 0.7 mg per day for male patients or 1 mg per day for female patients

or

- ☐ The patient has had a Special Authority approval for somatropin for childhood deficiency in children and no longer meets the renewal criteria under this indication

and

- ☐ The patient has undergone appropriate treatment of other hormonal deficiencies and psychological illnesses

and

- ☐ The patient has severe growth hormone deficiency (see notes)

and

- ☐ The patient's serum IGF-I is more than 1 standard deviation below the mean for age and sex

and

- ☐ The patient has poor quality of life, as defined by a score of 16 or more using the disease-specific quality of life questionnaire for adult growth hormone deficiency (QoL-AGHDA®)

Note: For the purposes of adults and adolescents, severe growth hormone deficiency is defined as a peak serum growth hormone level of less than or equal to 3 mcg per litre during an adequately performed insulin tolerance test (ITT) or glucagon stimulation test.
Patients with one or more additional anterior pituitary hormone deficiencies and a known structural pituitary lesion only require one test. Patients with isolated growth hormone deficiency require two growth hormone stimulation tests, of which, one should be ITT unless otherwise contraindicated. Where an additional test is required, an arginine provocation test can be used with a peak serum growth hormone level of less than or equal to 0.4 mcg per litre.
The dose of somatropin should be started at 0.2 mg daily and be titrated by 0.1 mg monthly until the serum IGF-I is within 1 standard deviation of the mean normal value for age and sex; and
Dose of somatropin not to exceed 0.7 mg per day for male patients, or 1 mg per day for female patients.
At the commencement of treatment for hypopituitarism, patients must be monitored for any required adjustment in replacement doses of corticosteroid and levothyroxine.

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