RS1826 - Somatropin

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I confirm that the above details are correct:

Signed: Date:

HOSPITAL MEDICINES LIST RESTRICTIONS CHECKLIST

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRES	CRIE	RIBER PATIEN	ī:
Name:		Name:	
Ward	:	NHI:	
Som	atro	ropin	
Re-a	ssess equis	ION – growth hormone deficiency in children essment required after 12 months uisites (tick boxes where appropriate) Prescribed by, or recommended by an endocrinologist or paediatric endocrinologist or behavior endocrinologist or paediatric endocrinologist or paediatric endocrinologist or behavior endocrinologist or paediatric endocrinologist or behavior endocrinologist endocrinologi	logist, or in accordance with a protocol or guideline that has been
and	or	Growth hormone deficiency causing symptomatic hypoglycaemia, or wit cardiomyopathy, hepatic dysfunction) and diagnosed with GH < 5 mcg/l life, or from samples during established hypoglycaemia (whole blood glue) Height velocity < 25th percentile for age; and adjusted for bone age standards of Tanner and Davies (1985)	on at least two random blood samples in the first 2 weeks of cose < 2 mmol/l using a laboratory device)
		and A current bone age is < 14 years (female patients) or < 16 years (and Peak growth hormone value of < 5.0 mcg per litre in response to who are 5 years or older, GH testing with sex steroid priming is reand If the patient has been treated for a malignancy, they should be dilaboratory and radiological imaging appropriate for the malignancy not necessary or appropriate Appropriate imaging of the pituitary gland has been obtained	wo different growth hormone stimulation tests. In children quired sease free for at least one year based upon follow-up
Re-a	ssess equis	NUATION – growth hormone deficiency in children essment required after 12 months uisites (tick boxes where appropriate) Prescribed by, or recommended by an endocrinologist or paediatric endocrinologist endocrinologist or paediatric endocrinologist end	logist, or in accordance with a protocol or guideline that has been
	and and and	Height velocity is greater than or equal to 25th percentile for age (adjust hormone treatment, as calculated over six months using the standards of the hormone treatment, as calculated over six months using the standards of the hormone treatment, as calculated to 2.0 cm per year, as calculated and the hormone of the hormone treatment, as calculated the hormone of the hormone treatment, as calculated the hormone treatment, as calculated to 2.0 cm per year, as calculated the hormone of the hormone treatment, as calculated to 2.0 cm per year, as calculated the hormone treatment, as calculated to 2.0 cm per year, as calculated the hormone treatment, as calculated to 2.0 cm per year, as calculated to 2.0 cm per year, as calculated the hormone treatment, as calculated to 2.0 cm per year, as calculated the hormone treatment that the patients specialist considers is likely to 2.0 cm.	ed for bone age/pubertal status if appropriate) while on growth of Tanner and Davis (1985) over 6 months
INITIATION – Turner syndrome Re-assessment required after 12 months Prerequisites (tick boxes where appropriate) Prescribed by, or recommended by an endocrinologist or paediatric endocrinologist, or in accordance with a protocol or guideline that ha endorsed by the Health NZ Hospital.			logist, or in accordance with a protocol or guideline that has been
and	and and	O Height velocity is < 25th percentile over 6-12 months using the standard	s of Tanner and Davies (1985)

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PRES	CRIBE	R PAT	ENT:
Name	:	Nam	e:
Ward:		NHI:	
Som	atropi	in - continued	
Re-a	ssessme	FION – Turner syndrome sent required after 12 months ses (tick boxes where appropriate)	
and		escribed by, or recommended by an endocrinologist or paediatric endoc dorsed by the Health NZ Hospital.	rinologist, or in accordance with a protocol or guideline that has been
	and _	Height velocity greater than or equal to 50th percentile for age (while Ranke's Turner Syndrome growth velocity charts)	e on growth hormone calculated over 6 to 12 months using the
	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
		No malignancy has developed since starting growth hormone	
INITIATION – short stature without growth hormone deficiency Re-assessment required after 12 months Prerequisites (tick boxes where appropriate) Prescribed by, or recommended by an endocrinologist or paediatric endocrinologist, or in accordance with a protocol or guideline that hendorsed by the Health NZ Hospital. and			rinologist, or in accordance with a protocol or guideline that has been
	and	The patient's height is more than 3 standard deviations below the m or delay	ean for age or for bone age if there is marked growth acceleration
	and	Height velocity is < 25th percentile for age (adjusted for bone age/prusing the standards of Tanner and Davies(1985)	bertal status if appropriate), as calculated over 6 to 12 months
	and	A current bone age is < 14 years (female patients) or < 16 years (m	ale patients)
	C	The patient does not have severe chronic disease (including malign medications known to impair height velocity	ancy or recognized severe skeletal dysplasia) and is not receiving
CON	TINUAT	FION – short stature without growth hormone deficiency	
Re-a	ssessme	nent required after 12 months es (tick boxes where appropriate)	
rieit	`	es (lick boxes where appropriate) escribed by, or recommended by an endocrinologist or paediatric endoc	rinologist, or in accordance with a protocol or guideline that has been
		dorsed by the Health NZ Hospital.	
	and	Height velocity is greater than or equal to 50th percentile (adjusted find 12 months using the standards of Tanner and Davies (1985)	or bone age/pubertal status if appropriate) as calculated over 6 to
	and	Height velocity is greater than or equal to 2 cm per year as calculate	d over six months
	and	Current bone age is 14 years or under (female patients) or 16 years	or under (male patients)
	C	No serious adverse effect that the patient's specialist considers is like	ely to be attributable to growth hormone treatment has occurred

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PRESCRIBER			PATIENT:	
Name:			Name:	
Ward:			NHI:	
Som	atropin	- continued		
INITI	ATION –	short stature due to chronic renal insufficiency nt required after 12 months (tick boxes where appropriate)		
and) Pres	. ,	adocrinologist or renal physician on the recommendation of a endocrinologist deline that has been endorsed by the Health NZ Hospital.	
	and	The patient's height is more than 2 standard deviations below	the mean	
	and	Height velocity is < 25th percentile (adjusted for bone age/pubstandards of Tanner and Davies (1985)	pertal status if appropriate) as calculated over 6 to 12 months using the	
	and	A current bone age is to 14 years or under (female patients) o	r to 16 years or under (male patients)	
	and	•	blic bone disease and absence of any other severe chronic disease	
	and	The patient is under the supervision of a specialist with expert		
	or	creatinine (umol/l × 40 = corrected GFR (ml/min/1.73 m²	1.73 m² as measured by the Schwartz method (Height(cm)/plasma ²) in a child who may or may not be receiving dialysis	
			eived < 5mg/ m² /day of prednisone or equivalent for at least 6 months	
		ON – short stature due to chronic renal insufficiency nt required after 12 months		
Prere	quisites	(tick boxes where appropriate)		
and		cribed by, or recommended by an endocrinologist, paediatric en aediatric endocrinologist, or in accordance with a protocol or gui	docrinologist or renal physician on the recommendation of a endocrinologist deline that has been endorsed by the Health NZ Hospital.	
;	and	Height velocity is greater than or equal to 50th percentile (adju 12 months using the standards of Tanner and Davies (1985)	sted for bone age/pubertal status if appropriate) as calculated over 6 to	
	O	Height velocity is greater than or equal to 2 cm per year as ca	culated over six months	
	and	A current bone age is 14 years or under (female patients) or 1	6 years or under (male patients)	
	and	No serious adverse effect that the patients specialist consider	s is likely to be attributable to growth hormone has occurred	
	and	No malignancy has developed after growth hormone therapy v	was commenced	
	and	The patient has not experienced significant biochemical or me	tabolic deterioration confirmed by diagnostic results	
	and	The patient has not received renal transplantation since starting	ng growth hormone treatment	
		If the patient requires transplantation, growth hormone prescribe made after transplantation based on the above criteria	ption should cease before transplantation and a new application should	

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PRESCRIBER		PATIENT:
Name:		Name:
Ward:		NHI:
Somatropin	- continued	
INITIATION – Re-assessmer Prerequisites Pres	Prader-Willi syndrome It required after 12 months (tick boxes where appropriate) cribed by, or recommended by an endocrinologist or paediatric or present by the Health NZ Hospital. The patient has a diagnosis of Prader-Willi syndrome that has The patient is aged six months or older A current bone age is < 14 years (female patients) or < 16 years Sleep studies or overnight oximetry have been performed and obstructive sleep disorder is found, it has been adequately treasurgeon The patient is aged two years or older and There is no evidence of type II diabetes or uncontrequal to 0.5 standard deviations in the preceding of the preceding of the patients of the preceding of th	ars (male patients) there is no obstructive sleep disorder requiring treatment, or if an ated under the care of a paediatric respiratory physician and/or ENT rolled obesity defined by BMI that has increased by greater than or 12 months and a thorough upper airway assessment is planned to be undertaken
Prerequisites Pres	Height velocity is greater than or equal to 50th percentile (adju 12 months using the standards of Tanner and Davies (1985) Height velocity is greater than or equal to 2 cm per year as cal A current bone age is 14 years or under (female patients) or 1. No serious adverse effect that the patient's specialist con side. No malignancy has developed after growth hormone therapy we have the properties of the patient's specialist con side.	6 years or under (male patients) rs is likely to be attributable to growth hormone treatment has occurred

HOSPITAL MEDICINES LIST RESTRICTIONS CHECKLIST

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PRESCRIBER	PATIENT:		
Name:	Name:		
Ward:	NHI:		
Somatropin - continued			
INITIATION – adults and adolescents Re-assessment required after 12 months			
Prerequisites (tick boxes where appropriate)			
Prescribed by, or recommended by an endocrinologist or pendorsed by the Health NZ Hospital.	paediatric endocrinologist, or in accordance with a protocol or guideline that has been		
	nt has undergone appropriate treatment of other hormonal deficiencies and psychological illnesses		
O The patient has severe growth hormone deficiency	The patient has severe growth hormone deficiency (see notes)		
The patient's serum IGF-I is more than 1 standard deviation below the mean for age and sex			
The patient has poor quality of life, as defined by a signowth hormone deficiency (QoL-AGHDA®)	score of 16 or more using the disease-specific quality of life questionnaire for adult		
equal to 3 mcg per litre during an adequately performed insulin toler Patients with one or more additional anterior pituitary hormone deficisolated growth hormone deficiency require two growth hormone sting an additional test is required, an arginine provocation test can be used the dose of somatropin should be started at 0.2 mg daily and be titted age and sex; and the dose of somatropin not to exceed 0.7 mg per day for male paties.	ciencies and a known structural pituitary lesion only require one test. Patients with mulation tests, of which, one should be ITT unless otherwise contraindicated. Where sed with a peak serum growth hormone level of less than or equal to 0.4 mcg per litre. rated by 0.1 mg monthly until it is within 1 standard deviation of the mean normal value		

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In the patient has been treated with somatropin for continued and or several factors such as external stressors) The patient has been treated with somatropin for continued and or the patient has been treated with somatropin for continued and or the patient has been treated with somatropin for continued and or the patient has been and or the patient has been treated with somatropin for continued and or the patient has been an improvement in the Quality of Life Assessment 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 or the Assessment of Growth Hormone Deficiency in Adults (QoL-AGHDA®) score from baseline and or the definition of the patient has been treated with somatropin for more than 12 months and or the patient has not had a deterioration in Quality of Life defined as a 8 point or greater increase from their lowest QoL-AGHDA® score on treatment (other than due to obvious external factors such as external stressors) 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 such as external stressors) 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 The patient has undergone appropriate treatment of other hormonal deficiencies and psychological illnesses and the patient has severe growth hormone deficiency (see notes) The patient has severe growth hormone deficiency (see notes) 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 (GoL-AGHDA®) to form the patient and adequately performed insulin toterance test (ITT) or quiceagon stimulation test. The patient was additional anterior pituitary hormone deficiencies and a known structural pituitary lesion only require one test. Patient	PRESCRIE	BER	, 3,	PATIENT:
CONTINUATION – adults and adolescents Re-assessment required after 12 months Prescribed by, or recommended by an endocrinologist or paediatric endocrinologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital. The patient has been treated with somatropin for < 12 months and The patient has been treated with somatropin for < 12 months There has been an improvement in the Quality of Life Assessment defined as a reduction of at least 8 points on the Quality of Life Assessment of Growth Hormone Deficiency in Adults (QoL-AGHDARi) score from baseline And The dose of somatropin does not exceed 0.7 mg per day for male patients, or 1 mg per day for female patients The patient has not had a deterioration in Quality of Life defined as a 6 point or greater increase from their lowest QoL-AGHDARis score from their lowest QoL-AGHDARis score from the patients and The patient has not had a deterioration in Quality of Life defined as a 6 point or greater increase from their lowest QoL-AGHDARis score on treatment (other than due to obvious external factors such as external stressors) The patient has not had a deterioration in Quality of Life defined as a 6 point or greater increase from their lowest QoL-AGHDARis score on treatment (other than due to obvious external factors such as external stressors) 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 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 The patient has severe growth hormone deficiency (see notes) The patient has severe growth hormone deficiency (Gee notes) The patient has severe growth hormone deficiency (Gee notes) The patient has poor quality of life, as defined by a score of 16 or more using the disease-specific quality of life authorized hormone deficiency (Geo-AGHDARis) The patient				Name:
CONTINUATION – adults and adolescents Re-assessment required after 12 months Prerequisites ((ick boxes where appropriate) Prescribed by, or recommended by an endocrinologist or paediatric endocrinologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital. The patient has been treated with somatropin for < 12 months There has been an improvement in the Quality of Life Assessment 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 Serum IGF-1 levels have increased to within ±1SD of the mean of the normal range for age and sex The dose of somatropin does not exceed 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 been treated with somatropin for more than 12 months and Serum IGF-1 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) 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 The patient has been treated in the service of the more manal range for age and sex (other than 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 The patient has undergone appropriate treatment of other hormonal deficiencies and psychological illnesses 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®) The patient has poor quality of life, as defined by a score of 16 or more using the disease-specific quality of lif				
CONTINUATION – adults and adolescents Re-assessment required after 12 months Prerequisites ((ick boxes where appropriate) Prescribed by, or recommended by an endocrinologist or paediatric endocrinologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital. The patient has been treated with somatropin for < 12 months There has been an improvement in the Quality of Life Assessment defined as a reduction of at least 8 points on the Quality of Life Assessment of Growth Hormone Deficiency in Adults (QoL-AQHDA®) score from baseline Serum IGF-1 levels have increased to within ±1SD of the mean of the normal range for age and sex The dose of somatropin does not exceed 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 been treated with somatropin for more than 12 months and Serum IGF-1 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) 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 The patient has been treated a special Authority approval for somatropin for childhood deficiency in children and no longer meets the renewal criteria under this indication The patient has severe growth hormone deficiency (see notes) The patient has severe growth hormone deficiency (see notes) 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®) 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®) The patient has poor quality of life, as defined by a score of 16 or more using the disease-specific quality of lies than or re				
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	Note: For equal to 3 Patients w isolated gran addition	ppin - con JATION - a Sment required to the prescribed dendorsed to the prescribed d	indults and adolescents irred after 12 months poxes where appropriate) by, or recommended by an endocrinologist or paediatric plants by the Health NZ Hospital. The patient has been treated with somatropin for < 12 months and the patient has been an improvement in the Quality of Life Asteroscopy in Adult Serum IGF-I levels have increased to within ±1SD of the The dose of somatropin does not exceed 0.7 mg per day. The patient has been treated with somatropin for more to the patient has not had a deterioration in Quality of Life score on treatment (other than due to obvious external factors) The dose of somatropin has not exceeded 0.7 mg per day. The patient has had a Special Authority approval for some patient has had a Special Authority approval for some patient has undergone appropriate treatment of other than that had a Special Authority approval for some patient has undergone appropriate treatment of other than that had a Special Authority approval for some patient has severe growth hormone deficiency (see the patient has poor quality of life, as defined by a score for adult growth hormone deficiency (QoL-AGHDA®) ses of adults and adolescents, severe growth hormone deficiencies are noted deficiency require two growth hormone stimulation to required, an arginine provocation test can be used with a growth and the provocation test can be used with a patient has experience and the control test can be used with a patient has poor quality of letter during an adequately performed insulin tolerance test and the patient has poor quality of life, as defined by a score for adult and and adolescents, severe growth hormone deficiencies are led to the patient has poor quality hormone deficiencies are led to the patient has poor quality hormone deficiencies are led to the patient has poor quality hormone deficiencies are led to the patient has poor quality hormone deficiencies are led to the patient has poor quality hormone deficiencies are led to the patient has poor quality hormone deficiencies are led to the patien	endocrinologist, or in accordance with a protocol or guideline that has been months sessesment defined as a reduction of at least 8 points on the Quality of ts (QoL-AGHDA®) score from baseline e mean of the normal range for age and sex y for male patients, or 1 mg per day for female patients defined as a 6 point or greater increase from their lowest QoL-AGHDA® actors such as external stressors) hin ±1SD of the mean of the normal range for age and sex (other than ay for male patients or 1 mg per day for female patients attropin for childhood deficiency in children and no longer meets the er hormonal deficiencies and psychological illnesses notes) tion below the mean for age and sex e of 16 or more using the disease-specific quality of life questionnaire officiency is defined as a peak serum growth hormone level of less than or (ITT) or glucagon stimulation test. da known structural pituitary lesion only require one test. Patients with sets, of which, one should be ITT unless otherwise contraindicated. Where peak serum growth hormone level of less than or equal to 0.4 mg per litre.