RS1826 - Somatropin

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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.

	PATIENT:
Name:	Name:
Ward:	NHI:
Somatropin	
INITIATION – growth hormone deficiency in childen Re-assessment required after 12 months	ren
Prerequisites (tick boxes where appropriate)	
O Prescribed by, or recommended by an endo endorsed by the Health NZ Hospital.	ocrinologist or paediatric endocrinologist, or in accordance with a protocol or guideline that has been
and	
cardiomyopathy, hepatic dysfunction)	symptomatic hypoglycaemia, or with other significant growth hormone deficient sequelae (e.g. and diagnosed with GH < 5 mcg/l on at least two random blood samples in the first 2 weeks of ed hypoglycaemia (whole blood glucose < 2 mmol/l using a laboratory device)
Height velocity < 25th percentil standards of Tanner and Davies	e for age; and adjusted for bone age/pubertal status if appropriate over 6 or 12 months using the s (1985)
A current bone age is < 14 yea	rs (female patients) or < 16 years (male patients)
O Peak growth hormone value of	< 5.0 mcg per litre in response to two different growth hormone stimulation tests. In children esting with sex steroid priming is required
If the patient has been treated to laboratory and radiological image not necessary or appropriate	for a malignancy, they should be disease free for at least one year based upon follow-up ging appropriate for the malignancy, unless there are strong medical reasons why this is either
Appropriate imaging of the pitul	itary gland has been obtained
CONTINUATION – growth hormone deficiency in Re-assessment required after 12 months Prerequisites (tick boxes where appropriate)	children
O Prescribed by, or recommended by an endo endorsed by the Health NZ Hospital.	ocrinologist or paediatric endocrinologist, or in accordance with a protocol or guideline that has been
	der (female patients) or 16 years or under (male patients)
Height velocity is greater than or equation hormone treatment, as calculated over	der (female patients) or 16 years or under (male patients) al to 25th percentile for age (adjusted for bone age/pubertal status if appropriate) while on growth er six months using the standards of Tanner and Davis (1985)
Height velocity is greater than or equal hormone treatment, as calculated over and Height velocity is greater than or equal to the second sec	al to 25th percentile for age (adjusted for bone age/pubertal status if appropriate) while on growth
and Height velocity is greater than or equation hormone treatment, as calculated over and Height velocity is greater than or equation and No serious adverse effect that the parameters and	al to 25th percentile for age (adjusted for bone age/pubertal status if appropriate) while on growth er six months using the standards of Tanner and Davis (1985)
Height velocity is greater than or equations and Height velocity is greater than or equations and Height velocity is greater than or equations.	al to 25th percentile for age (adjusted for bone age/pubertal status if appropriate) while on growth er six months using the standards of Tanner and Davis (1985) al to 2.0 cm per year, as calculated over 6 months tients specialist considers is likely to be attributable to growth hormone treatment has occurred
Height velocity is greater than or equations and Height velocity is greater than or equations and Height velocity is greater than or equations and No serious adverse effect that the parameter of the parameter o	al to 25th percentile for age (adjusted for bone age/pubertal status if appropriate) while on growth er six months using the standards of Tanner and Davis (1985) al to 2.0 cm per year, as calculated over 6 months tients specialist considers is likely to be attributable to growth hormone treatment has occurred
Height velocity is greater than or equations and Height velocity is greater than or equations and Height velocity is greater than or equations and No serious adverse effect that the parameter of the parameter o	al to 25th percentile for age (adjusted for bone age/pubertal status if appropriate) while on growth er six months using the standards of Tanner and Davis (1985) al to 2.0 cm per year, as calculated over 6 months tients specialist considers is likely to be attributable to growth hormone treatment has occurred
Height velocity is greater than or equations and Height velocity is greater than or equations and Height velocity is greater than or equations and No serious adverse effect that the paramoder of the paramoder o	al to 25th percentile for age (adjusted for bone age/pubertal status if appropriate) while on growth er six months using the standards of Tanner and Davis (1985) al to 2.0 cm per year, as calculated over 6 months tients specialist considers is likely to be attributable to growth hormone treatment has occurred starting growth hormone
Height velocity is greater than or equations and Height velocity is greater than or equations and Height velocity is greater than or equations and No serious adverse effect that the paramoder of the paramoder o	al to 25th percentile for age (adjusted for bone age/pubertal status if appropriate) while on growth er six months using the standards of Tanner and Davis (1985) al to 2.0 cm per year, as calculated over 6 months tients specialist considers is likely to be attributable to growth hormone treatment has occurred starting growth hormone starting growth hormone
Height velocity is greater than or equations and Height velocity is greater than or equations and Height velocity is greater than or equations and No serious adverse effect that the partial No malignancy has developed since and No malignancy has developed since and Re-assessment required after 12 months Prerequisites (tick boxes where appropriate) Prescribed by, or recommended by an endorendorsed by the Health NZ Hospital. The patient has a post-natal genotype and	al to 25th percentile for age (adjusted for bone age/pubertal status if appropriate) while on growth er six months using the standards of Tanner and Davis (1985) al to 2.0 cm per year, as calculated over 6 months tients specialist considers is likely to be attributable to growth hormone treatment has occurred starting growth hormone perinologist or paediatric endocrinologist, or in accordance with a protocol or guideline that has been be confirming Turner Syndrome

Signed: Date:

I confirm that the above details are correct:

Signed: Date:

HOSPITAL MEDICINES LIST RESTRICTIONS CHECKLIST

April 2025

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.

PRESCF	RIBER	P	ATIENT:
Name: .			ame:
Ward:		N	HI:
Somati	ropin	- continued	
Re-asse	Presciendors	sed by the Health NZ Hospital.	docrinologist, or in accordance with a protocol or guideline that has been while on growth hormone calculated over 6 to 12 months using the
ar		Height velocity is greater than or equal to 2 cm per year, calculate A current bone age is 14 years or under	ed over six months
ar	nd	No serious adverse effect that the specialist considers is likely to No malignancy has developed since starting growth hormone	be attributable to growth hormone treatment has occurred
Re-asse	Prescriendors Ond Ond Ond	The patient's height is more than 3 standard deviations below the or delay Height velocity is < 25th percentile for age (adjusted for bone age using the standards of Tanner and Davies(1985) A current bone age is < 14 years (female patients) or < 16 years	docrinologist, or in accordance with a protocol or guideline that has been a mean for age or for bone age if there is marked growth acceleration e/pubertal status if appropriate), as calculated over 6 to 12 months (male patients)
Re-asse	Presciendors ond ond ond	Height velocity is greater than or equal to 50th percentile (adjuste 12 months using the standards of Tanner and Davies (1985) Height velocity is greater than or equal to 2 cm per year as calcul Current bone age is 14 years or under (female patients) or 16 years	

HOSPITAL MEDICINES LIST RESTRICTIONS CHECKLIST

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lame:		. Name:
Vard:		. NHI:
omatropin	1 - continued	
Re-assessme	short stature due to chronic renal insufficiency nt required after 12 months s (tick boxes where appropriate)	
	scribed by, or recommended by an endocrinologist, paediatric aediatric endocrinologist, or in accordance with a protocol or o	endocrinologist or renal physician on the recommendation of a endocrinologist guideline that has been endorsed by the Health NZ Hospital.
and	The patient's height is more than 2 standard deviations belo	ow the mean
and	Height velocity is < 25th percentile (adjusted for bone age/p standards of Tanner and Davies (1985)	ubertal 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	or to 16 years or under (male patients)
and _	The patient is metabolically stable, has no evidence of meta-	abolic bone disease and absence of any other severe chronic disease
and	The patient is under the supervision of a specialist with exp	ertise in renal medicine
	_	
	The patient has a GFR less than or equal to 30 ml/mi creatinine (umol/l × 40 = corrected GFR (ml/min/1.73	n/1.73 m² as measured by the Schwartz method (Height(cm)/plasma m²) in a child who may or may not be receiving dialysis
or	creatinine (umol/l × 40 = corrected GFR (ml/min/1.73	n/1.73 m² as measured by the Schwartz method (Height(cm)/plasma m²) in a child who may or may not be receiving dialysis ecceived < 5mg/ m²/day of prednisone or equivalent for at least 6 months
	creatinine (umol/l × 40 = corrected GFR (ml/min/1.73 The patient has received a renal transplant and	m ²) in a child who may or may not be receiving dialysis
CONTINUATION Re-assessment	creatinine (umol/l × 40 = corrected GFR (ml/min/1.73	m ²) in a child who may or may not be receiving dialysis
CONTINUATION Re-assessment Prerequisites O Preserve or particular and particular	creatinine (umol/l × 40 = corrected GFR (ml/min/1.73 The patient has received a renal transplant and	m ²) in a child who may or may not be receiving dialysis eccived < 5mg/ m ² /day of prednisone or equivalent for at least 6 months endocrinologist or renal physician on the recommendation of a endocrinologis
CONTINUATION Re-assessment Prerequisites or particular of the control of the cont	creatinine (umol/l × 40 = corrected GFR (ml/min/1.73 The patient has received a renal transplant and has received a renal transplant and has received a renal transplant and has received after 12 months (tick boxes where appropriate) scribed by, or recommended by an endocrinologist, paediatric aediatric endocrinologist, or in accordance with a protocol or certain transplant and has received a renal transplant and has rece	eceived < 5mg/ m² /day of prednisone or equivalent for at least 6 months endocrinologist or renal physician on the recommendation of a endocrinologis guideline that has been endorsed by the Health NZ Hospital.
CONTINUATION Re-assessment Prerequisites or particular of the part	creatinine (umol/l × 40 = corrected GFR (ml/min/1.73 The patient has received a renal transplant and has received a renal transplant and has received after 12 months (tick boxes where appropriate) cribed by, or recommended by an endocrinologist, paediatric aediatric endocrinologist, or in accordance with a protocol or (the light velocity is greater than or equal to 50th percentile (a	m²) in a child who may or may not be receiving dialysis eccived < 5mg/ m² /day of prednisone or equivalent for at least 6 months endocrinologist or renal physician on the recommendation of a endocrinologis guideline that has been endorsed by the Health NZ Hospital. djusted for bone age/pubertal status if appropriate) as calculated over 6 to
CONTINUATION Re-assessment Prerequisites or part and and and and	creatinine (umol/l × 40 = corrected GFR (ml/min/1.73 The patient has received a renal transplant and has received a renal transplant and has received after 12 months (tick boxes where appropriate) cribed by, or recommended by an endocrinologist, paediatric aediatric endocrinologist, or in accordance with a protocol or (the interval of the interva	m²) in a child who may or may not be receiving dialysis eccived < 5mg/ m² /day of prednisone or equivalent for at least 6 months endocrinologist or renal physician on the recommendation of a endocrinologist guideline that has been endorsed by the Health NZ Hospital. djusted for bone age/pubertal status if appropriate) as calculated over 6 to
CONTINUATION Re-assessment Prerequisites or part of pa	creatinine (umol/l × 40 = corrected GFR (ml/min/1.73 The patient has received a renal transplant and has received a renal transplant and has received after 12 months (tick boxes where appropriate) Geribed by, or recommended by an endocrinologist, paediatric aediatric endocrinologist, or in accordance with a protocol or gerial telephologist, and the standards of Tanner and Davies (1985) Height velocity is greater than or equal to 50th percentile (a 12 months using the standards of Tanner and Davies (1985) Height velocity is greater than or equal to 2 cm per year as A current bone age is 14 years or under (female patients) or	m²) in a child who may or may not be receiving dialysis eccived < 5mg/ m² /day of prednisone or equivalent for at least 6 months endocrinologist or renal physician on the recommendation of a endocrinologist guideline that has been endorsed by the Health NZ Hospital. djusted for bone age/pubertal status if appropriate) as calculated over 6 to
CONTINUATION Re-assessment Prerequisites or parameters or	creatinine (umol/l × 40 = corrected GFR (ml/min/1.73 The patient has received a renal transplant and has received a renal transplant and has received after 12 months (tick boxes where appropriate) Geribed by, or recommended by an endocrinologist, paediatric aediatric endocrinologist, or in accordance with a protocol or gerial telephologist, and the standards of Tanner and Davies (1985) Height velocity is greater than or equal to 50th percentile (a 12 months using the standards of Tanner and Davies (1985) Height velocity is greater than or equal to 2 cm per year as A current bone age is 14 years or under (female patients) or	eceived < 5mg/ m² /day of prednisone or equivalent for at least 6 months endocrinologist or renal physician on the recommendation of a endocrinologist guideline that has been endorsed by the Health NZ Hospital. djusted for bone age/pubertal status if appropriate) as calculated over 6 to calculated over six months r 16 years or under (male patients) ers is likely to be attributable to growth hormone has occurred
CONTINUATION Re-assessment Prerequisites or parameters or	creatinine (umol/l × 40 = corrected GFR (ml/min/1.73 The patient has received a renal transplant and has received a renal transplant and has received after 12 months (tick boxes where appropriate) Secribed by, or recommended by an endocrinologist, paediatric aediatric endocrinologist, or in accordance with a protocol or generated the standards of Tanner and Davies (1985) Height velocity is greater than or equal to 50th percentile (a 12 months using the standards of Tanner and Davies (1985) Height velocity is greater than or equal to 2 cm per year as A current bone age is 14 years or under (female patients) or No serious adverse effect that the patients specialist considerations are considered.	m²) in a child who may or may not be receiving dialysis eccived < 5mg/ m² /day of prednisone or equivalent for at least 6 months endocrinologist or renal physician on the recommendation of a endocrinologist guideline that has been endorsed by the Health NZ Hospital. djusted for bone age/pubertal status if appropriate) as calculated over 6 to calculated over six months r 16 years or under (male patients) ers is likely to be attributable to growth hormone has occurred y was commenced
CONTINUATION Re-assessment Prerequisites or parameters or	creatinine (umol/l × 40 = corrected GFR (ml/min/1.73 The patient has received a renal transplant and has received a renal transplant and has received after 12 months (tick boxes where appropriate) Geribed by, or recommended by an endocrinologist, paediatric aediatric endocrinologist, or in accordance with a protocol or generated that the patients are as a current bone age is 14 years or under (female patients) or No serious adverse effect that the patients specialist considerated that the patients specialist considerated that the patients are created as a current bone age is 14 years or under (female patients) or No serious adverse effect that the patients specialist considerated that the patients are created as a current bone age is 14 years or under (female patients) or No serious adverse effect that the patients specialist considerated as a current bone age is 14 years or under (female patients) or No serious adverse effect that the patients specialist considerated as a current bone age is 14 years or under (female patients) or No serious adverse effect that the patients specialist considerated as a current bone age is 14 years or under (female patients) or No serious adverse effect that the patients specialist considerated as a current bone age is 14 years or under (female patients) or No serious adverse effect that the patients specialist considerated as a current bone age is 14 years or under (female patients) or No serious adverse effect that the patients are current bone as a current bone age is 14 years or under (female patients) or No serious adverse effect that the patients are current bone as a current bone age is 14 years or under (female patients) or No serious adverse effect that the patients are current bone as a current bone age is 14 years or under (female patients) or No serious adverse effect that the patients are current bone as a current bone age is 14 years or under (female patients) or No serious adverse effect that the patients are current bone as a current bone age is 14 years or und	eceived < 5mg/ m² /day of prednisone or equivalent for at least 6 months endocrinologist or renal physician on the recommendation of a endocrinologist guideline that has been endorsed by the Health NZ Hospital. djusted for bone age/pubertal status if appropriate) as calculated over 6 to calculated over six months r 16 years or under (male patients) ers is likely to be attributable to growth hormone has occurred by was commenced metabolic deterioration confirmed by diagnostic results

I confirm that the above details are correct:

Signed: Date:

HOSPITAL MEDICINES LIST RESTRICTIONS CHECKLIST

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PRESCRIBER	PATIENT:		
Name:	Name:		
/ard:NHI:			
Somatropin	- continued		
INITIATION – I Re-assessmen Prerequisites	Prader-Willi syndrome It required after 12 months (tick boxes where appropriate) cribed by, or recommended by an endocrinologist or paediatric endocrinologist, or in accordance with a protocol or guideline that has been resed by the Health NZ Hospital. The patient has a diagnosis of Prader-Willi syndrome that has been confirmed by genetic testing or clinical scoring criteria The patient is aged six months or older A current bone age is < 14 years (female patients) or < 16 years (male patients) 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		
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 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		
Re-assessment Prerequisites O Prese	ON – Prader-Willi syndrome It required after 12 months (tick boxes where appropriate) cribed by, or recommended by an endocrinologist or paediatric endocrinologist, or in accordance with a protocol or guideline that has been rised by the Health NZ Hospital.		
and O	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) Height velocity is greater than or equal to 2 cm per year as calculated over six months A current bone age is 14 years or under (female patients) or 16 years or under (male patients) No serious adverse effect that the patient's specialist con siders is likely to be attributable to growth hormone treatment has occurred No malignancy has developed after growth hormone therapy was commenced 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		

I confirm that the above details are correct:

Signed: Date:

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PRESCRIBER Name:	
Ward: NHI: NHI: NIII NHI: NHI: NHI: NHI: NHI	
Somatropin - continued INITIATION – adults and adolescents	
INITIATION – adults and adolescents	
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 the endorsed by the Health NZ Hospital. The patient has a medical condition that is known to cause growth hormone deficiency (e.g. surgical removal of the pituitary treatment of a pituitary tumour) and The patient has undergone appropriate treatment of other hormonal deficiencies and psychological illnesses and one of the patient's serum IGF-I is more than 1 standard deviation below the mean for age and sex and The patient's serum IGF-I is more than 1 standard deviation below the mean for age and sex 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 questionnair 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 les equal to 3 mog per litre during an adequately performed insulin tolerance test (ITT) or glueagon stimulation tests, or the patients with one or more additional anterior pitulary hormone deficiency is defined as a peak serum growth hormone test is required, an arginine provocation test can be used with a peak serum growth hormone test has considered an additional test is required, an arginine provocation test can be used with a peak serum growth hormone test with a required and under the deviation of the mean for age and sex; and The dose of somatropin should be started at 0.2 mg daily and be titrated by 0.1 mg monthly until it is within 1 standard deviation of the mean for age and sex; and	at has been for for e for adult ss than or ents with ted. Where ncg per litre. normal value

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Signed: Date:

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PRESC	RIBER		PATIENT:
Name:			Name:
Ward: .			NHI:
Somat	t ropin - cor	ntinued	
CONTI Re-ass	NUATION – a essment requ	adults and adolescents uired after 12 months coxes where appropriate)	
and		by, or recommended by an endocrinologist or paediatric by the Health NZ Hospital.	endocrinologist, or in accordance with a protocol or guideline that has been
	and	The patient has been treated with somatropin for < 12 r	months
	and	There has been an improvement in the Quality of Life Assessment of Growth Hormone Deficiency in Adul	ssessment defined as a reduction of at least 8 points on the Quality of tts (QoL-AGHDA®) score from baseline
	and	Serum IGF-I levels have increased to within ±1SD of the	e mean of the normal range for age and sex
		The dose of somatropin does not exceed 0.7 mg per da	y for male patients, or 1 mg per day for female patients
d	or	4	
	and	The patient has been treated with somatropin for more t	
	and	The patient has not had a deterioration in Quality of Life score on treatment (other than due to obvious external f	e defined as a 6 point or greater increase from their lowest QoL-AGHDA® factors such as external stressors)
	0	Serum IGF-I levels have continued to be maintained wit for obvious external factors)	hin ±1SD of the mean of the normal range for age and sex (other than
	and	The dose of somatropin has not exceeded 0.7 mg per d	lay for male patients or 1 mg per day for female patients
C	or O	The patient has had a Special Authority approval for sor renewal criteria under this indication	matropin for childhood deficiency in children and no longer meets the
	and	The patient has undergone appropriate treatment of oth	er hormonal deficiencies and psychological illnesses
	and	The patient has severe growth hormone deficiency (see	e notes)
	and	The patient's serum IGF-I is more than 1 standard devia	ation below the mean for age and sex
	and	The patient has poor quality of life, as defined by a scor for adult growth hormone deficiency (QoL-AGHDA®)	re of 16 or more using the disease-specific quality of life questionnaire
equal to Patient isolated an add The do mean r The do At the o	o 3 mcg per li s with one or d growth horm itional test is a se of somatro normal value of se of somatro	tre during an adequately performed insulin tolerance test more additional anterior pituitary hormone deficiencies are none deficiency require two growth hormone stimulation to required, an arginine provocation test can be used with a spin should be started at 0.2 mg daily and be titrated by 0 for age and sex; and spin not to exceed 0.7 mg per day for male patients, or 1 mg.	and a known structural pituitary lesion only require one test. Patients with ests, of which, one should be ITT unless otherwise contraindicated. Where peak serum growth hormone level of less than or equal to 0.4 mcg per litre. It is meaning monthly until the serum IGF-I is within 1 standard deviation of the