



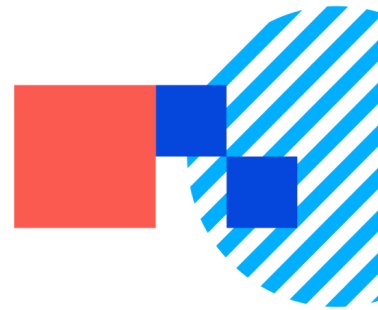
Growth Hormone Prior Authorization

Drug(s) Applied:	Genotropin (somatropin), Genotropin MiniQuick (somatropin)
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Criteria:

Drug(s) Applied will be approved when the requested medication is being used for a compendia supported indication and all of the following criteria are met:

- I. Initial Therapy Criteria for Children < 18 years old
 - A. **Growth hormone deficiency (GHD) in patients < 18yo** as indicated by chart notes within past 120 days
 1. Growth failure evidenced by ONE of the following:
 - a) Height > 2 Standard Deviations (SD) below the mean for age/sex
 - b) Height > 2 SD below the mean for age/sex and decrease in height SD of more than 0.5 SD over the past year
 - c) Height velocity (HV) > 2 SD below the mean for 1 year or >1.5 SD for 2 years **and**
 2. Patient meets ONE of the following:
 - a) Failed at least 2 GH stimulation tests (e.g., peak GH < 10 mcg/L after stimulation)
 - b) Failed at least 1 GH stimulation test (e.g., peak GH < 10 mcg/L after stimulation) and the patient has either a pathology of the central nervous system, received irradiation in the past, has other pituitary hormone defects, or has been diagnosed with a genetic defect
 - c) Documented auxological criteria, hypothalamic-pituitary defect (such as major congenital malformation, tumor or irradiation), and a known deficit of at least one other pituitary hormone **or**
 - d) Patient is a newborn with GHD due to congenital hypopituitarism with hypoglycemia, does not attain a serum GH concentration above 5 ug/L and has deficiency of at least one additional pituitary hormone and/or classical imaging triad (ectopic posterior pituitary and pituitary hypoplasia with abnormal stalk) **and**
 3. If 13 years of age or older, confirmation of open epiphyses as determined by imaging (e.g., MRI, x-ray) within the past year **and**
 4. Chart notes do not indicate that the patient has any of the following:
 - a) Acute critical illness due to complications following open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute



- respiratory failure **and**
- b) Active malignancy/cancerous tumors **and**
- c) Active proliferative or severe non-proliferative diabetic retinopathy **and**
- 5. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., endocrinology)

Approval Duration: 12 months

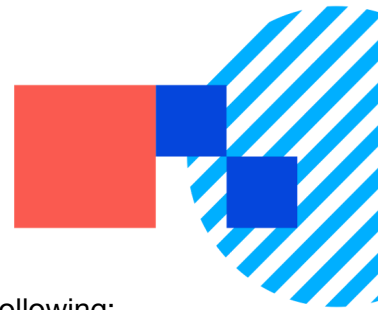
B. Idiopathic Short Stature (ISS) in patients < 18yo as indicated by chart notes within past 120 days

1. Patient is 5 years of age or older **and**
2. Chart notes do not indicate diagnostic evaluation includes other causes associated with short stature that should be observed or treated by other means **and**
3. If 13 years of age or older, confirmation of open epiphyses as determined by imaging (e.g., MRI, x-ray) within the past year **and**
4. Patient's baseline height \leq 1.2 percentile or SD \leq 2.25 for age and gender, **and**
5. Growth failure as evidenced by ONE of the following:
 - a) Patient has a growth rate $<$ 4 cm/year
 - b) Patient growth height velocity is less than the 25th percentile for age and gender based on at least 6 months of data
6. Chart notes indicate that the patient does not have any of the following:
 - a) Systemic, endocrine, or genetic cause or otherwise constitutional delay of growth and puberty **and**
 - b) Acute critical illness due to complications following open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure **and**
 - c) Active malignancy/cancerous tumors **and**
 - d) Active proliferative or severe non-proliferative diabetic retinopathy **and**
7. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., endocrinology)

Approval Duration: 6 months

C. Turner syndrome, Noonan syndrome, or Short Stature Homeobox-Containing Gene (SHOX) Deficiency in patients < 18yo as indicated by chart notes within past 120 days

1. Diagnosis confirmed by genetic testing **and**
2. If 13 years of age or older, confirmation of open epiphyses as determined by imaging (e.g., MRI, x-ray) within the past year **and**



3. Chart notes do not indicate that the patient has any of the following:
 - a) Acute critical illness due to complications following open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure **and**
 - b) Active malignancy/cancerous tumors **and**
 - c) Active proliferative or severe non-proliferative diabetic retinopathy **and**
4. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., endocrinology)

Approval Duration: 12 months

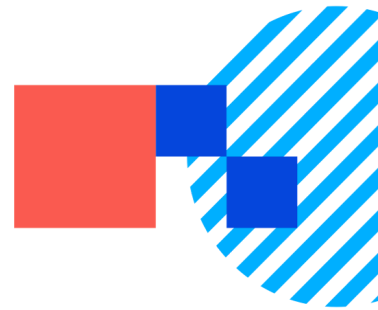
D. Short stature born small for gestational age (SGA) with no catch up growth by age 2-4 years in patients < 18yo as indicated by chart notes within past 120 days

1. Patient is 2 years of age or older, **and**
2. If 13 years of age or older, confirmation of open epiphyses as determined by imaging (e.g., MRI, x-ray) within the past year **and**
3. The birth weight and/or length were > 2 SD below the mean for gestational age and gender, **and**
4. Patient has failed to show catch up growth before age 2 (defined as a height velocity below 1 SD score, adjusted for age), **and**
5. Patient's baseline height is < 5th percentile for age and gender, **and**
6. Chart notes do not indicate that the patient has any of the following:
 - a) Acute critical illness due to complications following open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure **and**
 - b) Active malignancy/cancerous tumors **and**
 - c) Active proliferative or severe non-proliferative diabetic retinopathy **and**
7. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., endocrinology)

Approval Duration: 12 months

E. Prader-Willi syndrome in patients < 18yo as indicated by chart notes within past 120 days

1. Diagnosis confirmed by genetic testing **and**
2. If 13 years of age or older, confirmation of open epiphyses as determined by imaging (e.g., MRI, x-ray) within the past year **and**
3. Chart notes do not indicate that the patient has any of the following:
 - a) Acute critical illness due to complications following open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure **and**



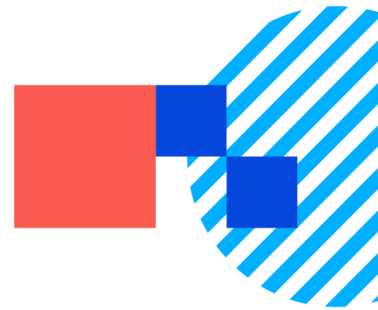
- b) Active malignancy/cancerous tumors **and**
 - c) Active proliferative or severe non-proliferative diabetic retinopathy **and**
 - d) Severe obesity (BMI \geq 120% of the 95th percentile for age and sex or \geq 35 kg/m², whichever is lower) or untreated or acute severe respiratory concerns **and**
4. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., endocrinology)

Approval Duration: 12 months

II. Initial Therapy Criteria for Adults > 18 years old

A. Growth hormone deficiency (GHD) in adults as indicated by chart notes within past 120 days

1. ONE of the following is supported in submitted chart notes:
 - a) Patient had a diagnosis of childhood-onset growth hormone deficiency, where persistent GHD is documented by at least one failed GH stimulation test performed at least 3 months after the cessation of prior GH therapy
 - b) Patient has adult-onset GHD associated with low GH levels as documented by failure of at least two GH stimulation tests (excluding 24-hour continuous measurements of GH, serum-levels of IGF-1, or serum levels of IGFBP-3, which are insufficient to demonstrate GH deficiency)
 - c) Patient has failed at least one GH stimulation test or has a low insulin-like growth factor-1 (IGF-1) level below 80 ng/ml and ONE of the following:
 - (1) Organic hypothalamic-pituitary disease
 - (2) Pituitary structural lesion or trauma
 - (3) The patient has panhypopituitarism or multiple pituitary hormone deficiency (deficiencies in \geq 3 pituitary axes) requiring hormone replacement therapy
 - (4) Patient has hypothalamic-pituitary structural defect other than ectopic posterior pituitary **and**
2. Chart notes do not indicate that the patient has any of the following:
 - a) Acute critical illness due to complications following open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure **and**
 - b) Active malignancy/cancerous tumors **and**
 - c) Active proliferative or severe non-proliferative diabetic retinopathy **and**
3. Prescriber is a specialist or has consulted with a specialist in the area of the



patient's diagnosis (e.g., endocrinology)

Approval Duration: 12 months

III. Continued Therapy Criteria for Children < 18 years old

A. **Growth hormone deficiency (GHD) in patients < 18yo** as indicated by chart notes within past 12 months

1. Patient meets the initial therapy criteria above **and**
2. Chart notes supplied indicate patient has been on requested drug as continuation of therapy and has documented clinical benefit with agent (e.g., increased height and/or height velocity) **and**
3. Patient does not have idiopathic short stature without evidence of biologic impairment of the growth hormone pituitary axis, **and**
4. Patient's epiphyses are open
 - a) Validation by imaging (e.g., MRI, x-ray) necessary if patient is aged 13 or older and have not grown in the past year **and**
5. Chart notes do not indicate that the patient has any of the following:
 - a) Acute critical illness due to complications following open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure **and**
 - b) Active malignancy/cancerous tumors **and**
 - c) Active proliferative or severe non-proliferative diabetic retinopathy **and**
6. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., endocrinology)

Approval Duration: 12 months

B. **Idiopathic Short Stature (ISS) in patients < 18yo** as indicated by chart notes within past 90 days

1. Patient meets the initial therapy criteria above **and**
2. Chart notes supplied demonstrate clinical benefit with agent through ONE of the following:
 - a) Patient's annual growth rate has doubled in comparison to the previous (baseline) year, or
 - b) Patient's height has increased by ≥ 2 cm/year in the most recent year **and**
3. Patient is 5 years of age or older, **and**
4. If 13 years of age or older, confirmation of open epiphyses as determined by imaging (e.g., MRI, x-ray) within the past year **and**
5. Chart notes do not indicate that the patient has any of the following:



- a) Systemic, endocrine, or genetic cause or otherwise constitutional delay of growth and puberty **and**
 - b) Acute critical illness due to complications following open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure **and**
 - c) Active malignancy/cancerous tumors **and**
 - d) Active proliferative or severe non-proliferative diabetic retinopathy **and**
6. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., endocrinology)

Approval Duration: 12 months

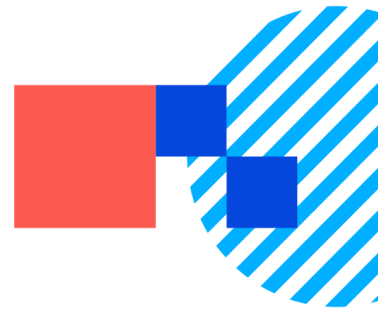
C. Turner syndrome, Noonan syndrome, or Short Stature Homeobox-Containing Gene (SHOX) Deficiency in patients < 18yo as indicated by chart notes within past 12 months

1. Chart notes supplied indicate patient has been on requested drug as continuation of therapy and has documented clinical benefit with agent (e.g., increased height and/or height velocity) **and**
2. If 13 years of age or older, confirmation of open epiphyses as determined by imaging (e.g., MRI, x-ray) within the past year **and**
3. Chart notes do not indicate that the patient has any of the following:
 - a) Acute critical illness due to complications following open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure **and**
 - b) Active malignancy/cancerous tumors **and**
 - c) Active proliferative or severe non-proliferative diabetic retinopathy **and**
4. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., endocrinology)

Approval Duration: 12 months

D. Short stature born small for gestational age (SGA) with no catch up growth by age 2-4 years in patients < 18yo as indicated by chart notes within past 90 days

1. Chart notes supplied indicate patient has been on requested drug as continuation of therapy and has documented clinical benefit as patient's height has increased by at least 2 cm/year in the most recent year **and**
2. If 13 years of age or older, confirmation of open epiphyses as determined by imaging (e.g., MRI, x-ray) within the past year **and**
3. The birth weight and/or length were more than 2 standard deviations (SD) below the mean for gestational age, **and**
4. Patient has failed to show catch up growth by age 2 (defined as a height velocity



below 1 SD score, adjusted for age), **and**

5. Chart notes do not indicate that the patient has any of the following:
 - a) Acute critical illness due to complications following open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure **and**
 - b) Active malignancy/cancerous tumors **and**
 - c) Active proliferative or severe non-proliferative diabetic retinopathy **and**
6. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., endocrinology)

Approval Duration: 12 months

E. Prader-Willi syndrome in patients < 18yo as indicated by chart notes within past 12 months

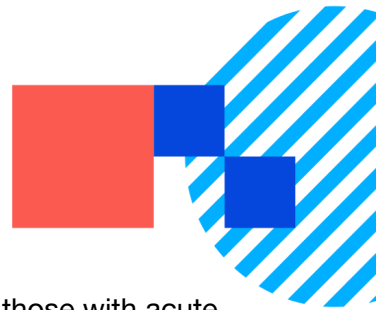
1. Chart notes supplied indicate patient has been on requested drug as continuation of therapy and has documented clinical benefit with agent (e.g., increased height and/or height velocity) **and**
2. If 13 years of age or older, confirmation of open epiphyses as determined by imaging (e.g., MRI, x-ray) within the past year **and**
3. Chart notes do not indicate that the patient has any of the following:
 - a) Acute critical illness due to complications following open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure **and**
 - b) Active malignancy/cancerous tumors **and**
 - c) Active proliferative or severe non-proliferative diabetic retinopathy **and**
 - d) Severe obesity or have severe respiratory concerns **and**
4. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., endocrinology)

Approval Duration: 12 months

IV. Continued Therapy Criteria for Adults > 18 years old

A. Growth hormone deficiency (GHD) in adults as indicated by chart notes within past 12 months

1. Patient meets the initial therapy criteria above **and**
2. Chart notes supplied indicate patient has been on requested drug as continuation of therapy and has documented clinical benefit with agent (i.e., improvement in lean body mass, bone mineral density, serum cholesterol) **and**
3. Chart notes do not indicate that the patient has any of the following:
 - a) Acute critical illness due to complications following open heart surgery,



- abdominal surgery or multiple accidental trauma, or those with acute respiratory failure **and**
- b) Active malignancy/cancerous tumors **and**
- c) Active proliferative or severe non-proliferative diabetic retinopathy **and**
- 4. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., endocrinology)

Approval Duration: 12 months

Policy Owned by: Curative PBM team