



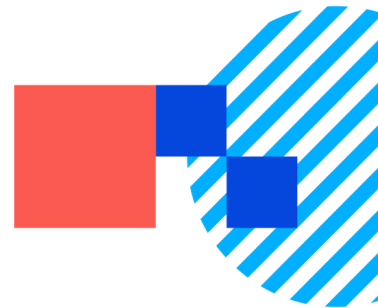
## Growth Hormone Prior Authorization

<b>Drug(s) Applied:</b>	<b>Genotropin (somatropin), Genotropin MiniQuick (somatropin)</b>
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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 (yo))
  - A. **Growth hormone deficiency (GHD) in patients < 18yo** as indicated by chart notes within past 90 days
    1. Patient has extreme short stature as evidenced by ONE of the following:
      - a) Height > 2 Standard Deviations (SD) below the mean for age/sex or a decrease in height SD > 0.5 over 1 year (for children >2 years)
      - b) Height > 1.5 SD below the midparental height
      - c) Height velocity (HV) >2 SD below the mean for 1 year, or >1.5 SD for 2 years
      - d) Downward deviation of height-for-age curve by 2 major percentiles (e.g., from above 25th to below 10th percentile)
      - e) Patient is aged 2-4 years and has a HV < 5.5 cm/year (less than 2.2 inches/year)
      - f) Patient is aged 4-6 years and has a HV < 5 cm/year (less than 2 inches/year)
      - g) Patient is male and is aged 6 years to puberty with a HV < 4 cm/year (less than 1.6 inches/year)
      - h) Patient is female and is aged 6 years to puberty with a HV < 4.5 cm/year (less than 1.8 inches/year) **and**
    2. Significantly reduced IGF-1 and IGFBP-3 (e.g., less than -2 SD) evidenced by 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) The patient has a documented pituitary abnormality and a known deficit of at least one other pituitary hormone **and**



3. 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**
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)

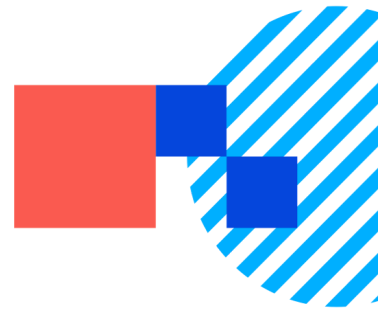
**Approval Duration:** 12 months

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

1. Patient is 5 years of age or older, **and**
2. 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**
3. Patient's baseline height  $\leq 1.2$  percentile or SD  $\leq 2.25$  for age and gender, **and**
4. Patient has extreme short stature 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 10th percentile for age and gender based on at least 6 months of data
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:** 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 90



days

1. 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**
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

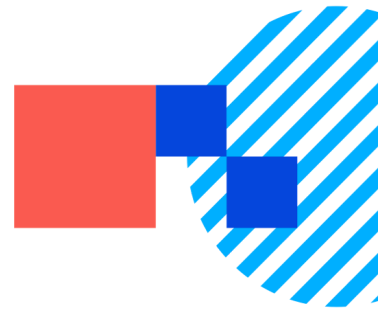
**D. Short stature born small for gestational age (SGA) with no catch up growth by age 2-4 years in patients < 18yo** as indicated by chart notes within past 90 days

1. Patient is 2 years of age or older, **and**
2. 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**
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 90 days

1. 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**

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**
  - d) Severe obesity (BMI  $\geq$  120% of the 95th percentile for age and sex or  $\geq$  35 kg/m<sup>2</sup>, whichever is lower) or untreated or acute severe respiratory concerns **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

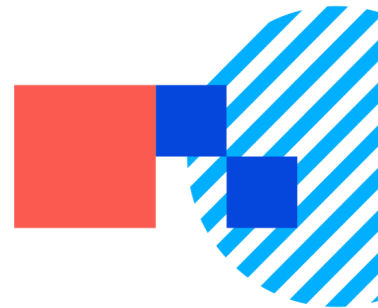
**F. Short bowel syndrome (SBS) in patients < 18yo** as indicated by chart notes within past 30 days

1. Patient is receiving specialized nutritional support **and**
2. 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**
3. ONE of the following:
  - a) Patient has tried and had an inadequate response to cyproheptadine or megestrol acetate, **or**
  - b) Patient has an intolerance or FDA labeled contraindication to both cyproheptadine and megestrol acetate **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., gastroenterology)

**Approval Duration:** 4 weeks

**G. Growth failure due to chronic kidney disease in patients < 18yo** as indicated by chart notes within past 90 days

1. Patient's height velocity (HV) for age is less than -1.88 standard deviations (SD)



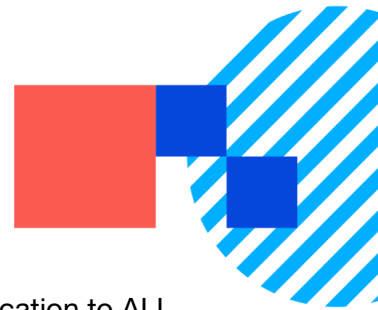
- or HV for age is less than the third percentile **and**
- 2. Patient's epiphyses are open
  - a) Validation by imaging (e.g., MRI, x-ray) necessary if patient is aged 13 or older and have not grown in the past year **and**
- 3. The patient has not undergone kidney transplantation within the past 12 months **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

## II. Initial Therapy Criteria for Adults (aged 18 years or older)

### A. AIDS wasting/cachexia in adults as indicated by chart notes within past 60 days

- 1. Patient is currently treated with antiretroviral therapy and will continue antiretroviral therapy in combination with the requested agent **and**
- 2. All other causes of weight loss have been ruled out & ONE of the following contexts applies:
  - a) Patient has had an unintentional weight loss of either 10 % of their initial body weight over 12 months or 7.5% of their initial body weight over 6 months
  - b) Patient has a body cell mass (BCM) loss greater than or equal to 5% within 6 months
  - c) Patient's sex is male and has BCM less than 35% of total body weight and body mass index (BMI) less than 27 kg/m<sup>2</sup>
  - d) Patient's sex is female and has BCM less than 23% of total body weight and BMI less than 27 kg/m<sup>2</sup>
  - e) Prescriber has provided information that the patient's BCM less than 35% or less than 23% and BMI less than 27 kg/m<sup>2</sup> are medically appropriate for diagnosing AIDS wasting/cachexia for the patient's sex
  - f) Patient's BMI is less than 20 kg/m<sup>2</sup> **and**
- 3. ONE of the following:
  - a) Patient has tried and had an inadequate response to at least one of the following alternatives: cyproheptadine, dronabinol, megestrol acetate, **or**



- b) Patient has an intolerance or FDA labeled contraindication to ALL alternative therapies (cyproheptadine, dronabinol, megestrol acetate) **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., infectious disease)

**Approval Duration:** 12 weeks

**B. Short bowel syndrome (SBS) in adults** as indicated by chart notes within past 30 days

- 1. Patient is receiving specialized nutritional support **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., gastroenterology) **and**
- 4. Patient has not previously received 4 weeks of treatment with human growth hormone

**Approval Duration:** 4 weeks

**C. Growth hormone deficiency (GHD) in adults** as indicated by chart notes within past 90 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 has been previously approved for the requested agent through the plan's Prior Authorization process or 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 Statue (ISS) in patients < 18yo** as indicated by chart notes within past 90 days

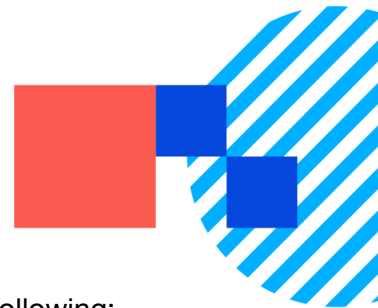
1. Patient has been previously approved for the requested agent through the plan's Prior Authorization process or meets the initial therapy criteria above **and**
2. Chart notes supplied demonstrate clinical benefit with agent through ONE of the following:
  - a) Patient's annual growth rate has doubled in comparison to the previous (baseline) year, or
  - b) Patient's height has increased by  $\geq 2$  cm/year in the most recent year **and**
3. Patient is 5 years of age or older, **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) 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. 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**





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

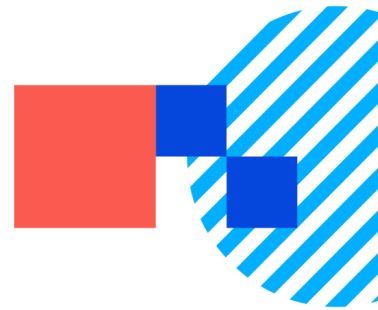
**D. Short stature born small for gestational age (SGA) with no catch up growth by age 2-4 years in patients < 18yo** as indicated by chart notes within past 90 days

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. 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**
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. 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**

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

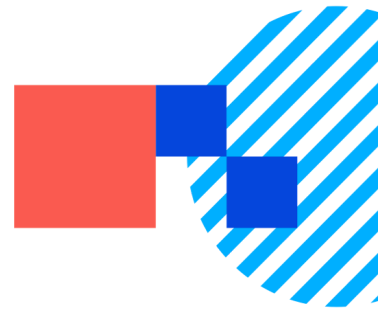
**F. Short bowel syndrome (SBS) in patients < 18yo** as indicated by chart notes within past 30 days

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization process or 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., decreased dependence on parenteral nutrition) **and**
3. Patient continues to receive specialized nutritional support **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., gastroenterology) **and**

**Approval Duration:** 4 weeks

**G. Growth failure due to chronic kidney disease in patients < 18yo** as indicated by chart notes within past 12 months

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization process or 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'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**
  4. The patient has not undergone kidney transplantation within the past 12 months **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)

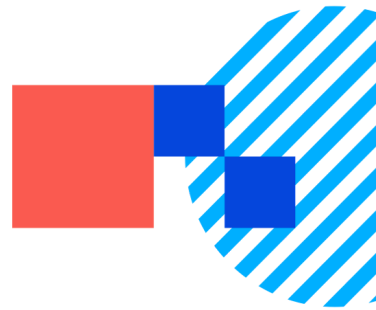
**Approval Duration:** 12 months

#### IV. Continued Therapy Criteria for Adults (aged 18 years or older)

- A. AIDS wasting/cachexia in adults** as indicated by chart notes within past 60 days
1. Patient has been previously approved for the requested agent through the plan's Prior Authorization process or 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., improved weight gain or weight stabilization) **and**
  3. Patient continues to use antiretroviral therapy in combination with the agent **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**
  5. 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., HIV)

**Approval Duration:** 12 weeks

- B. Short bowel syndrome (SBS) in adults** as indicated by chart notes within past 30 days
1. Patient has been previously approved for the requested agent through the plan's Prior Authorization process or 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.,



decreased dependence on parenteral nutrition) **and**

3. Patient continues to receive specialized nutritional support **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., gastroenterology)

**Approval Duration:** 4 weeks

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

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization process or 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 body composition, hip-to-waist ratio, cardiovascular health, bone mineral density, serum cholesterol, physical strength) **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