

CRITERIA FOR PRIOR AUTHORIZATION

Somatropin Products

PROVIDER GROUP Pharmacy

MANUAL GUIDELINES All dosage forms of the following drugs require prior authorization:
 Somatropin (Genotropin[®], Humatrope[®], Norditropin[®], Nutropin[®], Omnitrope[®], Saizen[®], Tev-Tropin[®], Zomacton[®])

Prior Authorization for Initiation of Growth Hormone in Children**CRITERIA FOR PEDIATRIC GROWTH HORMONE DEFICIENCY (GHD):** (must meet all of the following)

- Patient must have been evaluated by a Pediatric Endocrinologist or Pediatrician limiting practice to pediatric endocrinology.
- Must have radiological evidence of open epiphyseal growth plates (>16 for boys and >15 for girls).
- Diagnosis must be presented upon request and at least one of the following criteria is met:
 - Child has severe short stature with height standard deviation score (SDS) more than 3 SDS below the mean for chronological age and sex
 - Height more than 1.5 SDS below the mid-parental height
 - Child has moderate growth retardation with height more than 2 SDS below the mean and a height velocity over 1 year more than 1 SDS below the mean for chronological age, or a decrease in height SDS of more than 0.5 over 1 year in children over 2 years of age;
 - In the absence of short stature, a height velocity more than 2 SDS below the mean over 1 year or more than 1.5 SDS sustained over 2 years
 - Child has decreasing growth rate combined with a predisposing condition such as previous cranial irradiation or tumor
 - Child exhibits evidence of other pituitary hormone deficiencies or signs of congenital GHD (hypoglycemia, microphallus, prolonged jaundice, traumatic delivery)
- Normal thyroid function tests (TSH 0.4-4.0 mIU/L)
- Failure to respond to 2 growth hormone secretagogues with peak < 10ng/mL
 - MRI required for neonatal growth hormone deficiency AND those with peak < 5ng/mL
 - EXCEPTION: neonatal hypopituitarism/hypoglycemia where either GH peak < 10ng/mL during documented hypoglycemia is indication of GH deficiency OR documented structural abnormalities of the pituitary/hypothalamus (ectopic neurohypophysis, septo-optic dysplasia, or other midline defects)
- Request should be for any of the following:
 - Tev-Tropin[®], Omnitrope[®], Humatrope[®], Norditropin[®], Nutropin[®], Saizen[®], Genotropin[®], Zomacton[®]

CRITERIA FOR PANHYPOPITUITARISM: (must meet all of the following)

- Patient must have been evaluated by a Pediatric Endocrinologist or Pediatrician limiting practice to pediatric endocrinology.
- Must have radiological evidence of open epiphyseal growth plates (>16 for boys and >15 for girls).
- Diagnosis must be presented upon request.
- Patient must have documented deficiencies of AT LEAST one pituitary hormone; TSH, ACTH, LH/FSH, ADH.
 - Deficiencies in thyroid and Cortisol must be treated before performance of the GH stimulation test.
- Degree of GH deficiency must be documented by response to 2 GH secretagogues:
 - Patient must be on stable doses of other replacement hormones before performing stimulation tests.
 - Normal thyroid levels documented before testing (TSH 0.4-4.0 mIU/L).
 - < 5ng/mL = severe and < 10ng/mL = deficiency

APPROVED PA Criteria

- EXCEPTION: – neonatal hypopituitarism/hypoglycemia where either GH peak < 10ng/ml during documented hypoglycemia is indication of GH deficiency or documented structural abnormalities of the pituitary/hypothalamus (ectopic neurohypophysis, septo-optic dysplasia, or other midline defects). Deficiency can be documented by failure to respond to secretagogues but is not required

CRITERIA FOR CHRONIC RENAL INSUFFICIENCY (CRI): (must meet all of the following)

- Patient must have been evaluated by a Pediatric Endocrinologist or Pediatrician limiting practice to pediatric endocrinology.
- Must have radiological evidence of open epiphyseal growth plates (>16 for boys and >15 for girls).
- Diagnosis must be presented upon request.
- Patient must have a confirmed diagnosis of CRI by a Pediatric Nephrologist.
- Height velocity < 25th percentile for age:
 - Requires at least 6 months of growth data
 - Growth curve must be submitted
- Request must be for one of the following:
 - Nutropin®

CRITERIA FOR TURNER OR NOONAN SYNDROME: (must meet all of the following)

- Patient must have been evaluated by a Pediatric Endocrinologist or Pediatrician limiting practice to pediatric endocrinology.
- Must have radiological evidence of open epiphyseal growth plates (>16 for boys and >15 for girls).
- Diagnosis must be presented upon request.
- Patient must have a confirmed diagnosis of Turner or Noonan syndrome by karyotype.
- Patient must have normal thyroid function tests (TSH 0.4-4.0 mIU/L).
- Height velocity < 25th percentile for age or height < 5th percentile:
 - Requires at least 6 months of growth data
 - Growth curve must be submitted
- Request must be for one of the following:
 - Turner Syndrome
 - Omnitrope®, Humatrope®, Norditropin®, Nutropin®, Genotropin®, Zomacton®
 - Noonan Syndrome
 - Norditropin®

CRITERIA FOR PRADER-WILLI SYNDROME (PWS): (must meet all of the following)

- Patient must have been evaluated by a Pediatric Endocrinologist or Pediatrician limiting practice to pediatric endocrinology.
- Must have radiological evidence of open epiphyseal growth plates (>16 for boys and >15 for girls).
- Diagnosis must be presented upon request.
- Patient must have a confirmed diagnosis of PWS by a Geneticist.
- Patient must have normal thyroid function tests (TSH 0.4-4.0 mIU/L).
- DEXA scan for body composition
- Absence of obstructive sleep apnea by sleep study or treated obstructive sleep apnea
- Height velocity < 25th percentile for age or height < 5th percentile:
 - Requires at least 6 months of growth data
 - Growth curve must be submitted
- Request must be for one of the following:
 - Omnitrope®, Genotropin®, Norditropin®

APPROVED PA Criteria

CRITERIA FOR SMALL FOR GESTATIONAL AGE (SGA): (must meet all of the following)

- Patient must have been evaluated by a Pediatric Endocrinologist or Pediatrician limiting practice to pediatric endocrinology.
- Must have radiological evidence of open epiphyseal growth plates (>16 for boys and >15 for girls).
- Diagnosis must be presented upon request.
- Birth weight of less than 2,500 g at a gestational age of more than 37 weeks or a birth weight or length below the 3rd percentile for gestational age.
- Failure to manifest catch-up growth to reach normal height range by age 2
- Request must be for one of the following:
 - Omnitrope®, Genotropin®, Norditropin®, Zomacton®, Nutropin®

CRITERIA FOR SHORT STATURE HOMEBOX-CONTAINING GENE (SHOX) DEFICIENCY: (must meet all of the following)

- Patient must have been evaluated by a Pediatric Endocrinologist or Pediatrician limiting practice to pediatric endocrinology.
- Must have radiological evidence of open epiphyseal growth plates (>16 for boys and >15 for girls).
- Diagnosis must be presented upon request.
- Patient must have a confirmed diagnosis of SHOX by a Geneticist.
- Patient must have normal thyroid function tests (TSH 0.4-4.0 mIU/L).
- Height velocity < 25th percentile for age or height < 5th percentile:
 - Requires at least 6 months of growth data
 - Growth curve must be submitted
- Request must be for one of the following:
 - Humatrope®, Zomacton®

Length of Approval: 6 months

Prior Authorization for Renewal of Growth Hormone in Children

- Renewal of GH in children:
 - History and physical notes, and growth curve from pediatric endocrinologist dated within 6 months of request
 - Documented catch-up growth unless at target height percentile
- Rationale for discontinuing GH therapy, only one of the following must be met:
 - Growth velocity < 2cm/year while on GH therapy
 - There are persistent and uncorrectable problems with adherence to GH treatment. Compliance is defined as greater than or equal to 85% adherence to regimen (no more than one missed dose per week on average)
 - Prescriber must attest to patient adherence, and prescription claims data may be used to verify adherence
 - Recommendations of treating pediatric nephrologist or endocrinologist due to changes in underlying conditions
 - If there is poor response to treatment, generally defined as an increase in growth velocity of less than 50% from baseline, in the first year of therapy. In children with PWS, evaluation of response to therapy should also take into account whether body composition (i.e., ratio of lean to fat mass) has significantly improved
 - Evidence of epiphyseal closure
 - Expected final adult height has been reached, as defined by reaching the calculated mid-parental height* or reaching the 25th percentile of the adult height based on sex**, whichever comes first

Length of Renewal: 12 months

Prior Authorization for Growth Hormone in Adults

- Must be prescribed by or in consultation with an endocrinologist
- Patient must have one of the following:
 - diagnosis of pituitary insufficiency confirmed by growth hormone stimulation test (< 5ng/mL serum concentration) and below normal IGF-1/IGFBP3 (see table for normal ranges)
 - diagnosis of panhypopituitarism including those with surgical or radiological eradication of pituitary confirmed by MRI or CT scan
- Member has a perceived impairment of quality of life (QoL), as demonstrated by a reported score of at least 11 in the disease-specific 'Quality of life assessment of growth hormone deficiency in adults' (QoL-AGHDA) questionnaire
- If non-preferred Growth Hormone medication is being requested, then the Growth Hormone PDL form must also be completed and submitted for processing. Clinical Reviewers will follow established PDL guidelines. (Please note that for non-preferred drug requests the documentation must meet established clinical and PDL criteria to be approved. For requests for preferred drug then only the established clinical criteria must be met.)
- Request must be for one of the following:
 - Omnitrope®, Humatrope®, Norditropin®, Nutropin®, Saizen®, Genotropin®, Zomacton®

Length of Approval: 12 months

Notes:

- Mid parental height calculation:
 - For Boy:
 - In inches: (Father's Height + Mother's Height + 5) / 2
 - In cm: (Father's Height + Mother's Height + 13) / 2
 - For Girl
 - In inches: (Father's Height - 5 + Mother's Height) / 2
 - In cm: (Father's Height - 13 + Mother's Height) / 2
 - 25th percentile of adult height based on CDC growth chart is defined as 5'8" (172 cm) for boys and 5'2.5" (159 cm) for girls
- The use of growth hormone for diagnosis of idiopathic short stature (ISS) is not considered medically necessary and therefore is not covered under the Pharmacy benefit. This is an administrative denial and the review is not based upon medical necessity.

DRUG UTILIZATION REVIEW COMMITTEE CHAIR

PHARMACY PROGRAM MANAGER
DIVISION OF HEALTH CARE FINANCE
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

DATE

DATE

IGF-1 Normal Ranges by Age

Age Range	IGF-1 Normal Range
16-24	182-780 ng/mL
25-39	114-492 ng/mL
40-54	90-360 ng/mL
55+	71-290 ng/mL

IGFBP3 Normal Ranges by Age

Age Range	IGFBP3 Normal Range
18 years	3.1-7.9 mcg/mL
19 years	2.9-7.3 mcg/mL
20 years	2.9-7.2 mcg/mL
21-25 years	3.4-7.8 mcg/mL
26-30 years	3.5-7.6 mcg/mL
31-35 years	3.5-7.0 mcg/mL
36-40 years	3.4-6.7 mcg/mL
41-45 years	3.3-6.6 mcg/mL
46-50 years	3.3-6.7 mcg/mL
51-55 years	3.4-6.8 mcg/mL
56-60 years	3.4-6.9 mcg/mL
61-65 years	3.2-6.6 mcg/mL
66-70 years	3.0-6.2 mcg/mL
71-75 years	2.8-5.7 mcg/mL
76-80 years	2.5-5.1 mcg/mL
81-85 years	2.2-4.5 mcg/mL