Clinical Policy: Somatropin (Recombinant Human Growth Hormone)

Reference Number: CP.PHAR.55
Effective Date: 03/11
Last Review Date: 06/17
Line of Business: Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

The following are recombinant human growth hormones requiring prior authorization: somatropin (Genotropin®, Humatrope®, Norditropin®, Nutropin AQ®, Omnitrope®, Saizen®, Serostim®, Zomacton™, Zorbtive®).

FDA approved indication

Somatropin is a recombinant human growth hormone indicated for treatment of the following conditions in children and adults:

- Children:
  - Growth failure due to inadequate endogenous growth hormone (GH) secretion
  - Prader-Willi syndrome
  - Short stature associated with Turner syndrome
  - Short stature associated with Noonan syndrome
  - Short stature or growth failure associated with short stature homeobox-containing gene (SHOX) deficiency
  - Growth failure in children born small for gestational age who fail to manifest catch-up growth by 2-4 years of age
  - Growth failure associated with chronic renal insufficiency (CRI) up until the time of renal transplantation
  - Idiopathic short stature (non-GH-deficient short stature) defined by height standard deviation score ≤ -2.25 and growth rates unlikely to permit attainment of adult height in the normal range
- Adults:
  - Growth hormone deficiency
    - Adult-Onset (AO): Patients who have GH deficiency (GHD), either alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary disease, hypothalamic disease, surgery, radiation therapy, or trauma; or
    - Childhood-Onset (CO): Patients who were GH deficient during childhood as a result of congenital, genetic, acquired, or idiopathic causes.
      Patients who were treated with somatropin for GHD in childhood and whose epiphyses are closed should be reevaluated before continuation of somatropin therapy at the reduced dose level recommended for GH deficient adults. According to current standards, confirmation of the diagnosis of adult GHD in both groups involves an appropriate GH provocative test with two exceptions: (1) patients with multiple other pituitary hormone deficiencies due to organic disease; and (2) patients with congenital/genetic GHD.
  - Short bowel syndrome (SBS) in patients receiving specialized nutritional support

- HIV (human immunodeficiency virus) patients with wasting or cachexia with concomitant antiviral therapy

Policy/Criteria
Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Centene Corporation® that somatropin (recombinant human growth hormone (rhGH)) is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Neonatal Hypoglycemia (must meet all)**:**

1. Prescribed by or in consultation with an endocrinologist;
2. Diagnosis of neonatal hypoglycemia;
3. Brain MRI shows risk for hypopituitarism;
4. Random GH measurement of < 20 µg/L;
5. Causes of hypoglycemia, other than GHD, have been ruled out;
6. Prescribed rhGH dose does not exceed 0.4 mg/kg/week;
7. If prescription is for an rhGH product other than Norditropin, the Norditropin formulations are inappropriate (e.g., due to preservatives or dosing increment limitations) or member has a contraindication or clinically significant adverse effects to Norditropin;
8. No contraindications per Appendix B.

Approval duration: up to 12 months total

B. Growth Hormone Deficiency - Children (must meet all)**:**

1. Prescribed by or in consultation with an endocrinologist;
2. Epiphyses are open;
3. Evidence of short stature/growth failure per Appendix C;
4. Diagnosis of GHD;
5. Other causes of growth failure have been ruled out (e.g., chronic systemic disease, undernutrition, hypothyroidism, Turner syndrome - in girls, skeletal disorders);
6. Intracranial tumor is excluded by MRI (magnetic resonance imaging) or CT (computed tomography);
7. Low or low normal insulin-like growth factor (IGF)-I or insulin-like growth factor binding protein (IGFBP)-3 level and one of the following:
   a. Two GH stimulation tests with peak levels ≤ 10 µg/mL;
   b. Evidence of ≥ 3 pituitary hormone deficiencies;
   c. History of surgery or irradiation in the hypothalamic-pituitary region;
   d. Defined central nervous system pathology documented by MRI or CT;
   e. Documented genetic cause of GHD;
8. Prescribed rhGH dose does not exceed either of the following:
   a. 0.7 mg/kg/week if pubertal;
   b. 0.4 mg/kg/week if prepubertal;
9. If prescription is for an rhGH product other than Norditropin, the Norditropin formulations are inappropriate (e.g., due to preservatives or dosing increment

limitations) or member has a contraindication or clinically significant adverse effects to Norditropin;
10. No contraindications per Appendix B.

Approval duration: 12 months

C. Growth Hormone Deficiency – Adults and Transition Patients (must meet all)**:**
1. Prescribed by or in consultation with an endocrinologist;
2. Diagnosis of AO or CO GHD;
3. One of the following (i, ii or iii):
   i. Two GH stimulation tests with peak levels ≤ 5 µg/mL;
   ii. Both of the following:
      a) One GH stimulation test with a peak level ≤ 5 µg/ml;
      b) One low IGF-I level;
   iii. One low IGF-I level and one of the following:
      a) Hypothalamic-pituitary structural lesions;
      b) Evidence of ≥ 3 pituitary hormone deficiencies;
      c) Documented genetic cause of GHD;
4. If prescription is for an rhGH product other than Norditropin, the Norditropin formulations are inappropriate (e.g., due to preservatives or dosing increment limitations) or member has a contraindication or clinically significant adverse effects to Norditropin;
5. No contraindications per Appendix B.

Approval duration: 12 months

D. Genetic Diseases with Primary Effects on Growth - Children (must meet all)**:**
1. Prescribed by or in consultation with an endocrinologist;
2. Epiphyses are open;
3. One of the following diagnoses:
   i. Prader-Willi syndrome (PWS):
      a) Confirmed by genetic testing;
      b) None of the following apply:
         1) Severe obesity;
         2) History of upper airway obstruction;
         3) History of sleep apnea;
         4) Severe respiratory impairment;
      c) Prescribed rhGH dose does not exceed 0.3 mg/kg/week;
   ii. Turner syndrome:
      a) Confirmed by genetic testing;
      b) Evidence of short stature or growth failure per Appendix C;
      c) Prescribed rhGH dose does not exceed 0.5 mg/kg/week;
   iii. Noonan syndrome:
      a) Confirmed by genetic testing or diagnosed by a geneticist;
      b) Evidence of short stature or growth failure per Appendix C;
      c) Prescribed rhGH dose does not exceed 0.5 mg/kg/week;
   iv. SHOX deficiency:
      a) Confirmed by genetic testing;

b) Evidence of short stature or growth failure per Appendix C;
c) Prescribed rhGH dose does not exceed 0.4 mg/kg/week;

4. If prescription is for an rhGH product other than Norditropin, the Norditropin formulations are inappropriate (e.g., due to preservatives or dosing increment limitations) or member has a contraindication or clinically significant adverse effects to Norditropin;
5. No contraindications per Appendix B.

Approval duration: 12 months

E. Prader-Willi Syndrome - Adults and Transition Patients (must meet all)**:**

1. Prescribed by or in consultation with an endocrinologist;
2. Diagnosis of PWS confirmed by genetic testing;
3. Epiphyses are closed;
4. rGH therapy will be titrated to maintain normal range IGF-1 level for age and sex matched controls;
5. Member has none of the following:
   i. Severe obesity;
   ii. Uncontrolled diabetes;
   iii. Untreated severe sleep apnea;
   iv. Active psychosis;
6. If prescription is for an rhGH product other than Norditropin, the Norditropin formulations are inappropriate (e.g., due to preservatives or dosing increment limitations) or member has a contraindication or clinically significant adverse effects to Norditropin;
7. No contraindications per Appendix B.

Approval duration: 12 months

F. Born Small for Gestational Age - Children (must meet all)**:**

1. Prescribed by or in consultation with an endocrinologist;
2. Epiphyses are open;
3. Diagnosed as small for gestational age (SGA);
4. Birth weight or length > 2 standard deviations (SD) below the mean for gestational age;
5. Failure to manifest catch-up growth to reach normal height range by age 2;
6. Prescribed rhGH dose does not exceed 0.5 mg/kg/week;
7. If prescription is for an rhGH product other than Norditropin, the Norditropin formulations are inappropriate (e.g., due to preservatives or dosing increment limitations) or member has a contraindication or clinically significant adverse effects to Norditropin;
8. No contraindications per Appendix B.

Approval duration: 12 months

G. Chronic Kidney Disease – Children (must meet all)**:**

1. Prescribed by or in consultation with an endocrinologist or nephrologist;
2. Epiphyses are open;
3. Evidence of short stature or growth failure per Appendix C;

4. Diagnosis of chronic kidney disease (CKD) as evidenced by one of the following:
   i. Structural or functional abnormalities of the kidney for ≥ 3 months;
   ii. GFR < 60 mL/min per 1.73 m^2 for ≥ 3 months;
   iii. Occurrence of a and b together of any duration;
5. Prescribed in conjunction with optimal CKD management (e.g., metabolic, endocrine and nutritional abnormalities have been treated and stabilized);
6. Member does not have a functioning renal allograft;
7. Prescribed rhGH dose does not exceed 0.4 mg/kg/week;
8. If prescription is for an rhGH product other than Norditropin, the Norditropin formulations are inappropriate (e.g., due to preservatives or dosing increment limitations) or member has a contraindication or clinically significant adverse effects to Norditropin;
9. No contraindications per Appendix B.

Approval duration: 12 months

H. Short Bowel Syndrome (must meet all):
1. Prescribed by or in consultation with a gastroenterologist;
2. Diagnosis of SBS;
3. Age ≥ 18 years;
4. Member's SBS therapeutic plan requires specialized nutritional support;
5. Prescribed rhGH dose does not exceed 8 mg/day;
6. If prescription is for an rhGH product other than Norditropin, the Norditropin formulations are inappropriate (e.g., due to preservatives or dosing increment limitations) or member has a contraindication or clinically significant adverse effects to Norditropin;
7. No contraindications per Appendix B.

Approval duration: 3 months

I. HIV-Related Wasting or Cachexia (must meet all):
1. Prescribed by or in consultation with a physician specializing in HIV diagnosis and management;
2. Diagnosis of HIV-related wasting or cachexia;
3. Age ≥ 18 years;
4. Unexplained weight loss of > 10% body weight from baseline;
5. Treatment with therapies other than rhGH have been suboptimal;
6. Alternate causes of wasting or cachexia have been ruled out;
7. Currently receiving antiretroviral therapy;
8. Prescribed rhGH dose does not exceed 6 mg/day;
9. If prescription is for an rhGH product other than Norditropin, the Norditropin formulations are inappropriate (e.g., due to preservatives or dosing increment limitations) or member has a contraindication or clinically significant adverse effects to Norditropin;
10. No contraindications per Appendix B.

Approval duration: up to 3 months total

J. Other diagnoses/indications

1. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Neonatal Hypoglycemia (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Documentation of positive response to therapy;
3. Prescribed rhGH dose does not exceed 0.4 mg/kg/week.

Approval duration: up to 12 months total

B. Growth Hormone Deficiency - Children (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Documented adherence and positive response to rhGH therapy;
3. If treatment for ≥ 1 year, both of the following (i and ii):
   i. Height velocity > 2 cm/year;
   ii. Bone age ≤ 15 years if girl or ≤ 17 years if boy;
4. Prescribed rhGH dose does not exceed:
   i. If pubertal - 0.7 mg/kg/week;
   ii. If non-pubertal - 0.4 mg/kg/week.

Approval duration: 12 months

C. Growth Hormone Deficiency - Adults (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Documented adherence and positive response to rhGH therapy;
3. Normalization of IGF-1 levels if low prior to rhGH therapy;
4. One of the following:
   i. Decreased body fat;
   ii. Increased bone density;
   iii. Improved endurance;
   iv. Less fatigue.

Approval duration: 12 months

D. Genetic Diseases with Primary Effects on Growth - Children (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Documented adherence and positive response to rhGH therapy;
3. If treatment for ≥ 1 year, both of the following (i and ii):
   i. Height velocity > 2 cm/year;
   ii. Bone age ≤ 15 years if girl or ≤ 17 years if boy;
4. Prescribed rhGH dose does not exceed:
   i. PWS - 0.3 mg/kg/week;
   ii. Turner syndrome - 0.5 mg/kg/week;
   iii. SHOX deficiency - 0.4 mg/kg/week;

iv. Noonan syndrome - 0.5 mg/kg/week.

Approval duration: 12 months

E. Prader-Willi Syndrome – Adults and Transition Patients (must meet all):
1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Documented adherence and positive response to rhGH therapy (e.g., positive effects on body composition, lipid metabolism, physical and psychosocial functioning relative to potential side effects including impairments of glucose metabolism, edema or heart disease);
3. IGF-1 is within the normal range for age and sex.

Approval duration: 12 months

F. Born Small for Gestational Age - Children (must meet all):
1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Documented adherence and positive response to rhGH therapy;
3. If treatment for ≥ 1 year, both of the following (i and ii):
   i. Height velocity > 2 cm/year;
   ii. Bone age ≤ 15 years if girl or ≤ 17 years if boy;
4. Prescribed rhGH dose does not exceed 0.5 mg/kg/week.

Approval duration: 12 months

G. Chronic Kidney Disease – Children (must meet all):
1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Documented adherence and positive response to rhGH therapy;
3. If treatment for ≥ 1 year, both of the following (i and ii):
   i. Height velocity > 2 cm/year;
   ii. Bone age ≤ 15 years if girl or ≤ 17 years if boy;
4. Prescribed rhGH dose does not exceed 0.4 mg/kg/week;
5. Member does not have a functioning renal allograft.

Approval duration: 12 months

H. Short Bowel Syndrome (must meet all):
1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Documented adherence and positive response to rhGH therapy;
3. Decreased specialized nutritional requirement as measured by total volume, total calories, or infusion frequency;
4. Prescribed dose does not exceed 8 mg/day.

Approval duration: up to 6 months total

I. HIV-Related Wasting or Cachexia (must meet all):
1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;

2. Documented adherence and positive response to rhGH therapy;
3. One of the following:
   i. Partial recovery of weight loss documented at baseline;
   ii. Improvement in body mass;
   iii. Improvement in nutritional status;
4. Currently receiving antiretroviral therapy;
5. Prescribed rhGH dose does not exceed 6 mg/day.

Approval duration: up to 3 months total

J. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PHAR.57 or evidence of coverage documents;
B. Idiopathic short stature (ISS);
C. Constitutional growth delay;
D. Obesity;
E. Adult short stature or altered body habitus associated with antiviral therapy;
F. Anabolic therapy to enhance body mass or strength for non-medical reasons (e.g., athletic gains).

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AO: Adult onset
CO: Childhood onset
CKD: chronic kidney disease
GFR: glomerular filtration rate
GH: growth hormone
GHD: growth hormone deficiency
HGH: human growth hormone
HIV: human immunodeficiency virus
IGF-1: insulin-like growth factor-1
IGFBP-3: insulin-like growth factor binding protein-3
PWS: Prader-Willi syndrome
rhGH: recombinant human growth hormone
SBS: short bowel syndrome
SD: standard deviation
SGA: small for gestational age
SHOX deficiency: short stature homeobox-containing gene deficiency

Appendix B: Contraindications to GH Therapy

- Hypersensitivity to somatropin or any diluents/excipients in the prescribed product
- Acute critical illness due to complications following open heart surgery, abdominal surgery or multiple accidental trauma
- Acute respiratory failure

- Active or suspected malignancy within the last 12 months
- Active proliferative or severe non-proliferative diabetic retinopathy

Appendix C: Short Stature/Growth Failure Criteria
Short stature/growth failure prior to rhGH therapy is evidenced by one of the following:
1. Height > 3 SD below the mean
2. Height > 2 SD below the mean and (a or b)
   a. Height velocity > 1 SD below the mean for chronological age over 1 year
   b. Decrease in height SD > 0.5 over 1 year in children > 2 years of age
3. Height > 1.5 SD below midparental height
4. Height velocity > 2 SD below the mean over 1 year
5. Height velocity > 1.5 SD below the mean over 2 years

V. Dosage and Administration

Somatropin, rhGH doses must be individualized and are highly variable depending on the nature and severity of the disease, the formulation being used, and on patient response. For specific dosage instructions, refer to the full prescribing information.

VI. Product Availability

Drug	Availability
Norditropin FlexPro	Solution, Subcutaneous: 5 mg/1.5 mL (1.5 mL); 10 mg/1.5 mL (1.5 mL); 15 mg/1.5 mL (1.5 mL); 30 mg/3 mL (3 mL) [contains phenol]
Nutropin AQ NuSpin 5	Solution, Subcutaneous: 5 mg/2 mL (2 mL) [contains phenol]
Nutropin AQ NuSpin 10	Solution, Subcutaneous: 10 mg/2 mL (2 mL) [contains phenol]
Nutropin AQ NuSpin 20	Solution, Subcutaneous: 20 mg/2 mL (2 mL) [contains phenol]
Nutropin AQ Pen	Solution, Subcutaneous: 10 mg/2 mL (2 mL); 20 mg/2 mL (2 mL) [contains phenol]
Omnitrope	Solution, Subcutaneous: 5 mg/1.5 mL (1.5 mL) [contains benzyl alcohol]; 10 mg/1.5 mL (1.5 mL) [contains phenol]
Humatrope	Solution Reconstituted, Subcutaneous: 5 mg (1 ea); 6 mg (1 ea); 12 mg (1 ea); 24 mg (1 ea) [contains glycerin, metacresol]
Saizen	Solution Reconstituted, Subcutaneous: 5 mg (1 ea); 8.8 mg (1 ea)
Saizen Click Easy	Solution Reconstituted, Subcutaneous: 8.8 mg (1 ea)
Genotropin:	Solution Reconstituted, Subcutaneous: 5 mg (1 ea); 12 mg (1 ea) [contains metacresol]
Omnitrope	Solution Reconstituted, Subcutaneous: 5.8 mg (1 ea)
Serostim	Solution Reconstituted, Subcutaneous: 4 mg (1 ea); 5 mg (1 ea); 6 mg (1 ea)
Zomacton	Solution Reconstituted, Subcutaneous: 5 mg (1 ea) [contains benzyl alcohol]; 10 mg (1 ea) [contains metacresol]
Zorbtive	Solution Reconstituted, Subcutaneous: 8.8 mg (1 ea) [contains benzyl alcohol]

Drug	Availability
Genotropin MiniQuick	Solution Reconstituted, Subcutaneous [preservative free]: 0.2 mg (1 ea); 0.4 mg (1 ea); 0.6 mg (1 ea); 0.8 mg (1 ea); 1 mg (1 ea); 1.2 mg (1 ea); 1.4 mg (1 ea); 1.6 mg (1 ea); 1.8 mg (1 ea); 2 mg (1 ea)

G. References

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
Changed preferred Growth Hormone from Norditropin to Tev-tropin	09/11	9/11
No clinical changes	10/12	10/12
Appendix K: deleted low-fat diet, added low oxalate diet. Appendix F: changed age of 2 to age of 4. Changed "normal range is typically considered ≥10th percentile to (height velocity SDS less than 0 during the past year. Growth failure due to CRI algorithm: fixed typo Appendix E PWS algorithm: changed first year response to GH therapy: Does patient change in height SDS >0.3, a 1 year height velocity ≥ 3 cm/y, or a height velocity SDS ≥ + 1 SGA algorithm: changed to Verify: Birth weight or length < 2 SDS for gestational age. Changed to Did patient fail to manifest catch-up growth by 3years of age. Removed delayed bone age requirement in Figure 2 for diagnosis of GHD	10/13	12/13
Combined "management challenges" and "current standards of practice" into one background section Figure 1: restructured review process to proceed to figure 2 or 10 depending on age of patient; added brain MRI or CT if pediatric Figure 2: allowed specific disease states to skip stimulation test questions since they are not relevant Figures 5 – 9: directed to re-auth algorithm if currently on med through Centene benefit to reduce redundancy Added Figure 16 to reduce redundancy in other algorithms Reformatted safety section Added Table 3 Updated Appendix D & F Added Appendix Q: Assessment of bone age Added Appendix R: Calculation of midparental height	12/14	12/14
Policy converted to new template. Increlex transferred to new policy.	11/15	Updates requested

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Tev-Tropin and Nutropin removed - no longer available. Criteria arranged by pediatric then adult initial/continuation therapy; in both sections, documentation requests and dose titration questions removed. Pediatric GH criteria - neonatal hypoglycemia/GHD as an indication is removed - considered off-label per Norditropin; specific growth failure/short stature requirements removed per expert review; midparental height removed per expert review; CKD criteria changed from GFR<75 to definition of CKD per KDOQI; changed initial and re-authorization approval periods to 12 months in response to CPC comment that was not in line with efficacy criteria measured after one year for re-auth. Adult GHD criteria – for childhood and adult onset GHD, require only low IGF-1 if defined structural lesions, multiple hormone deficiencies, etc. per expert review recommending no need for provocation test here.		
Committee review with recommendations 12/15, required specialist review. Updates: I.A: updated definitions of short stature and growth failure; changed age for treatment to open epiphyses instead of 18 year, I.B change bone age for girls to 15 and for boys 17 as these are the ages that 99% of growth has been completed.	01/16	02/16
Added table of contents and minor edit for clarity, no criteria changes	03/16	
Incorporated expert recommendations to clinical criteria: Listed genetic syndromes included in other causes of growth failure Expanded confirmation of Noonan syndrome to include geneticist diagnosis Clarified age requirement to 2 years for failure to manifest catch-up growth in children born small for gestational age Removed redundancies in criteria related to absence of short stature in pediatric patients Added maximum dosing criteria for growth hormone agents used for pediatric diagnoses as well as for Serostim and Zorbtive	04/16	
-Policy converted to new template. Products are made interchangeable with preference for Norditropin; Zomacton is added. -Neonatal hypoglycemia criteria is added. “Endogenous” is removed from childhood GHD.	05/16	06/16

Reviews, Revisions, and Approvals	Date	P&T Approval Date
-Childhood dosing is based on highest dose across PIs for a given indication. Neonatal hypoglycemia is based on GHD childhood dosing. Adult dosing is based on PIs for SBS and HIV; adult dosing is not included for GHD given the potential variability in required amounts. Dosing is titrated via height and IGF-1 levels in children and IGF-1 levels in adults. -Adult age requirement is required for HIV and SBS only; open epiphyses are required for all childhood diagnoses other than neonatal hypoglycemia. -Required GH stimulation tests, and IGF-1 and IGFBP-3 levels are edited as follows: for childhood GHD: two GH stim tests and either a low IGF-1 or IGFBP-3 level, or just a low IGf-1 level if additional risk factors; for adults, two GH stim tests, or one GH stim test and one IGF-1 level, or one IGF-1 level with additional risk factors. -Contraindications common to all indications are listed in App B. Contraindications specific to an indication are placed within the applicable criteria. Short stature/growth failure is moved to App B and is removed as a requirement from SGA. -Adult GHD approval period is lengthened from 3 to 12 months to give time for dose titration before re-auth. CKD diagnosis - option "c" (a combination of a and b without a duration requirement) is added. Removed requirement for normalized IGF-1 levels on continued approval for childhood GHD. -Specialist reviewed.		
Added criteria for adult and transition PWS to initial and continuation criteria per the GH Research Society PWS 2013 consensus statement.	09/16	09/16
Converted to new template. Re-auth: removed reasons to discontinue. Removed preexisting papilledema and concomitant administration of GH and Increlex from Appendix B.	05/17	06/17

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in

developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.