Clinical Policy: Somatropin (Human Growth Hormone)

Reference Number: IN.CP.PHAR.55
Effective Date: 01.21
Last Review Date: 12.21
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 (GH) requiring prior authorization: somatropin (Genotropin®, Humatrope®, Norditropin®, Nutropin AQ®, Omnitrope®, Saizen®, Serostim®, Zomacton®, Zorbtive®).

Drugs	Children								Adults		
	GHD	PWS	TS	NS	SHOX	CKD	SGA	ISS	GHD	HIV	SBS
Genotropin	GF	GF	GF				GF	GF	X		
Humatrope	SS/GF		SS/GF		SS/GF		SS/GF	SS/GF	X		
Norditropin	GF	GF	SS	SS			SS	SS	X		
NutropinAQ	GF		GF			GF		GF	X		
Omnitrope	GF	GF	GF				GF	GF	X		
Saizen	GF								X		
Serostim										X	
Zomacton	GF		SS		SS		SS	SS	X		
Zorbtive											X

Abbreviations: CKD: chronic kidney disease, GF: growth failure, GHD: growth hormone deficiency, HIV: human immunodeficiency virus, ISS: idiopathic short stature, NS: Noonan syndrome, PWS: Prader-Willi syndrome, SBS: short bowel syndrome, SGA: small for gestational age, SHOX: short stature homeobox-containing gene, SS: short stature, TS: Turner syndrome

FDA Approved Indication(s)

Genotropin is indicated for treatment of:

- Children with GF due to GHD, PWS, SGA, TS, and ISS.
- Adults with either childhood-onset (CO) or adult-onset (AO) GHD.

Humatrope is indicated for treatment of:

- Children with SS or GF associated with GHD, TS, ISS, SHOX deficiency, and failure to catch up in height after SGA birth.
- Adults with either CO or AO GHD.

Norditropin FlexPro is indicated for the treatment of:

- Children with GF due to GHD, SS associated with NS, SS associated with TS, SS born SGA with no catch-up growth by age 2 to 4 years, ISS, and GF due to PWS.
- Adults with either CO or AO GHD.

Nutropin AQ is indicated for the treatment of:

- Children with GF due to GHD, ISS, TS, and CKD up to the time of renal transplantation.
- Adults with either CO or AO GHD.

Omnitrope is indicated for the treatment of:
- Children with GF due to GHD, PWS, SGA, TS, and ISS.
- Adults with either CO or AO GHD.

Saizen is indicated for:
- Children with GF due to GHD.
- Adults with either CO or AO GHD.

Serostim is indicated for treatment of:
- HIV patients with wasting or cachexia to increase lean body mass and body weight, and improve physical endurance.

Zomacton is indicated for:
- Treatment of pediatric patients who have GF due to inadequate secretion of normal endogenous GH, SS associated with TS, ISS, SS or GF in SHOX deficiency, and SS born SGA with no catch-up growth by 2 years to 4 years.
- Replacement of endogenous GH in adults with GHD.

Zorbtive is indicate for treatment of:
- SBS in adult patients receiving specialized nutritional support.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Index

I. Initial Approval Criteria for Pediatric Patients (less 18 years old)

A. Must meet all of the following:

A. • Bone age of 14-15 or less in females, 16-17 or less in males (x-ray or preferably written documentation)

B. Epiphyses open (x-ray or preferably written documentation). Documented evidence of open epiphyses is needed only if patient is nearing or at puberty (estimated age range 10-17 years of age

C. One of the following diagnoses:
1.Growth Hormone Deficiency
2.Growth Retardation with Chronic Renal Insufficiency
3.Turner's syndrome
4.Noonan syndrome
5.SHOX (short stature homeobox-containing gene) deficiency
6.Growth Failure in Children Born Small for Gestational Age, Prader Willi syndrome

B Must meet all of the following

1. Documentation of height measurement prior to growth hormone therapy of more than 2.0 standard deviations below population mean for given age (growth chart)
2. Prescriber attestation that they have performed all necessary testing to ensure there are no expanding intracranial lesions or tumors
3. Growth rate of 5 cm/yr or less before start of therapy
4. Biochemical evidence or testing supporting the diagnosis

II. Continuing Approval Criteria for 18 years of age and younger

A. Must meet all of the following

1. Bone age of 14-15 or less in females, 16-17 or less in males (x-ray or preferably written documentation)
2. Epiphyses open (x-ray or preferably written documentation). Documented evidence of open epiphyses is needed only if patient is nearing or at puberty (estimated age range 10-16 years of age)
3. • One of the following diagnoses: Growth Hormone Deficiency, Growth Retardation with Chronic Renal Insufficiency, Turner's syndrome, Noonan syndrome, SHOX (short stature homeobox-containing gene) deficiency, Growth Failure in Children Born Small for Gestational Age, Prader - Willi syndrome.
4. Adult Growth Hormone Deficiency and the following: - Biochemical evidence or testing supporting the diagnosis

Or

B. Must meet all of the following:

1. Prescriber attestation that they have performed all necessary testing to ensure there are no expanding intracranial lesions or tumors
2. Growth rate of 2 to 2 & 1/2 cm/yr or more after initiation of therapy

III. Initial Coverage for Adults (18 years and older)

A. Must meet all of the following

1. Patient has reached adult height
2. Patient stopped growth hormone therapy for at least 1-month before re-evaluation of the need for continued therapy
3. Prescriber has determined that patient will experience growth hormone deficiency into adulthood and would receive clinical benefit from continued growth hormone therapy

B. • Diagnosis of HIV Wasting or Cachexia and all of the following:

1. Must have failed one other therapy for HIV wasting or cachexia (i.e., dronabinol, megestrol, or anabolic steroids)
2. Must be on AIDS anti-retroviral therapy
3. Must have involuntary weight loss of > 10% of baseline total body weight or body cell mass of < 30% for initial approval
4. Must have quantitative measurement of lean body mass using dual energy X-ray absorptiometry (DEXA) or bioelectric impedance analysis (BIA) prior to initiation of therapy

IV. Continuing Approval Criteria for 18 years of age and older Must meet all:

- **A.** Documentation that member continues on AIDS antiretroviral therapy. Can use claims history to verify.
- **B.** Documentation of current body weight or lean body mass
- **C.** Approve 12 months

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. 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 policies – CP.PMN.53 for Medicaid or evidence of coverage documents.
- **B.** Idiopathic short stature (ISS);
- **C.** Constitutional delay of growth and puberty (i.e., constitutional growth delay; the member's growth rate is delayed compared to chronological age but appropriate for bone age as determined by x-ray);
- **D.** Familial (genetic) short stature (i.e., height velocity and bone age, as determined by x-ray, are within the normal range and one or both parents are short);
- **E.** Adult short stature or altered body habitus associated with antiviral therapy (other than HIV-associated wasting or cachexia);
- **F.** Obesity treatment or enhancement of body mass/strength for non-medical reasons (e.g., athletic gains).

II. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CKD: chronic kidney disease
FDA: Food and Drug Administration
GFR: glomerular filtration rate
GH: growth hormone
GHD: growth hormone deficiency
HIV: human immunodeficiency virus
IGF-1: insulin-like growth factor-1
IGFBP-3: insulin-like growth factor binding protein-3
ISS: idiopathic short stature
NS: Noonan syndrome
PWS: Prader-Willi syndrome
rhGH: recombinant human growth hormone
SBS: short bowel syndrome
SD: standard deviation
SGA: small for gestational age
SHOX: short stature homeobox-containing gene
TS: Turner syndrome

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug	Dosing Regimen	Dose Limit/Maximum Dose
Appetite Stimulants		
Megestrol (Megace®)	400 - 800 mg PO daily (10 – 20 ml/day)	800 mg/day
Dronabinol (Marinol®)	2.5 mg PO bid	20 mg/day
Testosterone Replacement Products		
Testosterone enanthate or cypionate (Various brands)	50 - 400 mg IM Q2 – 4 wks	400 mg Q 2 wks
Androderm® (testosterone transdermal)	2.5 – 7.5 mg patch applied topically QD	7.5 mg/day
Androgel® (testosterone gel)	5 - 10 gm gel (delivers 50 – 100 mg testosterone) applied topically QD	10 gm/day gel (100 mg/day testosterone)
Testim® (testosterone gel)	5 - 10 gm gel (delivers 50 – 100 mg testosterone) applied topically QD	10 gm/day gel (100 mg/day testosterone)
Anabolic Steroids		
Oxandrolone (Oxandrin®)	2.5 – 20 mg PO /day	20 mg/day
Nandrolone decanoate	100 mg IM Q week	100 mg Q wk
Nausea/Vomiting Treatments*		
chlorpormazine	10 to 25 mg PO q4 to 6 hours prn	2,000 mg/day
perphenazine	8 to 16 mg/day PO in divided doses	64 mg/day
prochlorperazine	5 to 10 mg PO TID or QID	40 mg/day
promethazine	12.5 to 25 mg PO q4 to 6 hours prn	50 mg/dose; 100 mg/day
trimethobenzamide	300 mg PO TID or QID prn	1,200 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
**Preferred status may be formulary-specific.*

Appendix C: Contraindications/Boxed Warnings

- Somatropin agents contraindications:
  - Acute critical illness
  - Children with PWS who are severely obese or have severe respiratory impairment (reports of sudden death)
  - Active malignancy
  - Product hypersensitivity
  - Active proliferative or severe non-proliferative diabetic retinopathy
  - Children with closed epiphyses
- Sogroya contraindications:
  - Acute critical illness

- Active malignancy
- Hypersensitivity to somapacitan-beco or excipients
- Active proliferative or severe non-proliferative diabetic retinopathy

- Boxed warning(s): none reported

Appendix D: Short Stature and Growth Failure

- For SS, the policy follows the World Health Organization (WHO) definition of > 2 SD below the mean for age and sex.[1]
- For GF, the policy follows
  - Haymond et al (2013) and Rogol et al (2014) for height deceleration across two major percentiles representing a change of > 1 SD corrected for age and sex[2,3] and
  - the Growth Hormone Research Society (2000) for height velocity in the absence of SS that would prompt further investigation, namely, a height velocity > 2 SD below the mean over 1 year or > 1.5 SD below the mean sustained over 2 years for age and sex.[4]
- The Centers for Disease Control and Prevention (CDC) recommend WHO growth charts for infants and children age 0 to < 2 years and CDC growth charts for children age 2 years to < 20 years in the U.S.[5]
  - Based on CDC recommended growth chart data, SD approximations of major height percentiles falling below the mean are listed below:
    - 2nd percentile: 2 SD below the mean
    - 5th percentile: 1.5 SD below the mean
    - 15th percentile: 1 SD below the mean
    - 30th percentile: 0.5 SD below the mean
    - 50th percentile: 0 SD mean
  - CDC recommended growth charts, data tables, and related information that may be helpful in assessing length, height and growth are available at the following link: https://www.cdc.gov/growthcharts/index.htm.

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1. WHO Child Growth Standards: Length/Height-for-Age, Weight-for-Age, Weight-for-Length, Weight-for-Height and Body Mass Index-for-Age: Methods and Development. Geneva, Switzerland: World Health Organization; 2006. As cited in CDC. Division of Nutrition, Physical Activity, and Obesity. Growth Chart Training: Using the WHO Growth Charts. Page last reviewed April 15, 2015. Available at https://www.cdc.gov/nccdphp/dnpao/growthcharts/who/using/assessing_growth.htm. Accessed May 1, 2020.
2. Haymond M, Kappelgaard AM, Czernichow P, et al. Early recognition of growth abnormalities permitting early intervention. Acta Pædiatrica ISSN 0803-5253. April 2013. DOI:10.1111/apa.12266.
3. Rogol AD, Hayden GF. Etiologies ad early diagnosis of short stature and growth failure in children and adolescents. J Pediatr. 2014 May;164(5 Suppl):S1-14.e6. doi: 10.1016/j.jpeds.2014.02.027.
4. Consensus guidelines for the diagnosis and treatment of growth hormone (GH) deficiency in childhood and adolescence: summary statement of the GH Research Society. JCEM. 2000; 85(11): 3990-3993.
5. Centers for Disease Control and Prevention, National Center for Health Statistics. CDC growth charts: United States. http://www.cdc.gov/growthcharts/. Accessed April 22, 2020.

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Pediatric Indications (Subcutaneous administration; weekly doses should be divided)			
Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Saizen, Zomacton	GHD	G, O: 0.16 to 0.24 mg/kg/week H, Z: 0.18 to 0.30 mg/kg/week N: 0.17 to 0.24 mg/kg/week Nu: to 0.30 mg/kg/week S: 0.18 mg/kg/week	See dosing regimens
Genotropin, Norditropin, Omnitrope	PWS	G, N, O: 0.24 mg/kg/week	0.24 mg/kg/week
Genotropin, Humatrope, Norditropin, Omnitrope, Zomacton	SGA	G, O: to 0.48 mg/kg/week H, N, Z: to 0.47 mg/kg/week	0.48 mg/kg/week
Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Zomacton	TS	G, O: 0.33 mg/kg/week H, Nu, Z: to 0.375 mg/kg/week N: to 0.47 mg/kg/week	See dosing regimens
Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Zomacton	ISS	G, O, No: to 0.47 mg/kg/week H, Z: to 0.37 mg/kg/week Nu: to 0.30 mg/kg/week	See dosing regimens
Humatrope, Zomacton	SHOX	H, Z: 0.35 mg/kg/week	0.35 mg/kg/week
Norditropin	NS	0.46 mg/kg/week	0.46 mg/kg/week
Nutropin	CKD	0.35 mg/kg/week	0.35 mg/kg/week
Adult Indications (Subcutaneous administration)			
Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Saizen, Zomacton	GHD	0.4 mg/day - may adjust by increments up to 0.2 mg/day every 6 weeks to maintain normal IGF-1 serum levels.* _____ **Dosing regimen from Endocrine Society guidelines (Fleseriu, et al., 2016).* Adult GHD dosing should be substantially lower than that prescribed for children. Adult doses beyond 1.6 mg/day would be uncommon.	See dosing regimen
Serostim	HIV-associated wasting	0.1 mg/kg QOD or QD to 6 mg QD	6 mg/day up to 24 weeks
Zorbtive	SBS	0.1 mg/kg QD to 8 mg QD	8 mg/day up to 4 weeks

Abbreviations: G: genotropin, H: humatrope, N: norditropin, Nu: nutropin, O: omnitrope, S: saizen, Z: zomacton

VI. Product Availability

Drug	Availability
Genotropin lyophilized powder	Dual-chamber syringe: 5 mg, 12 mg
Genotropin Miniquick ***(without preservative)***	Pen cartridge: 0.2 mg, 0.4 mg, 0.6 mg, 0.8 mg, 1.0 mg, 1.2 mg, 1.4 mg, 1.6 mg. 1.8 mg, and 2.0 mg
Humatrope	Pen cartridge: 6 mg, 12 mg, 24 mg Vial: 5mg
Norditropin Flexpro	Pen: 5 mg/1.5 mL, 10 mg/1.5 mL, 15 mg/1.5 mL, 30 mg/3 mL
Nutropin AQ	NuSpin: 5 mg/2 mL, 10 mg/2 mL, 20 mg/2 mL
Omnitrope	Pen cartridge: 5 mg/1.5 mL, 10 mg/1.5 mL Vial: 5.8 mg
Saizen	Pen cartridge: 8.8 mg Vial: 5 mg, 8.8 mg
Serostim	Vial: 4 mg, 5 mg, 6 mg
Zomacton	Vial: 5 mg, 10 mg
Zorbtive	Vial: 8.8 mg

VII. References

FDA Labels

1. Genotropin Prescribing Information. NY, NY: Pfizer, Inc.; April 2019. Available at www.genotropin.com. Accessed October 29, 2019.
2. Humatrope Prescribing Information. Indianapolis, IN: Eli Lilly; December 2016. Available at: www.humatrope.com. Accessed October 29, 2019.
3. Norditropin Prescribing Information. Plainsboro, NJ: Novo Nordisk; February 2018. Available at: www.norditropin.com. Accessed October 29, 2019.
4. Nutropin AQ. Prescribing Information. South San Francisco, CA: Genentech; December 2016. Available at: www.nutropin.com. Accessed October 29, 2019.
5. Omnitrope Prescribing Information. Princeton, NJ: Sandoz; June 2019. Available at: www.omnitrope.com. Accessed October 29, 2019.
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Compendia

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16. National Kidney Foundation. KDOQI Clinical Practice Guideline for Nutrition in Children with CKD: 2008 Update. Am J Kidney Dis 53: S1-S124, 2009 (suppl 2).

GHD - Adults and Transition Patients
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Short Bowel Syndrome
20. Pironi L, Arends J, Bozzetti F. ESPEN guidelines on chronic intestinal failure in adults. Clinical Nutrition. 2016; 35:247-307.

HIV-Associated Wasting
21. Badowski ME, Perez SE. Clinical utility of dronabinol in the treatment of weight loss associated with HIV and AIDS. HIV AIDS (Auckl). 2016 Feb 10;8:37-45. doi: 10.2147/HIV.S81420. eCollection 2016.

Somatropin Product Comparative Data
22. Romer T, Zabransky M, Walczak M, Szalecki M, and Balser S. Effect of switching recombinant human growth hormone: comparative analysis of phase 3 clinical data. Biol Ther 2011; 1(2):005. DOI 10.1007/s13554-011-0004-8

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy converted to new template. Increlex transferred to new policy. 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	11.15	Updates requested

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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. 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	05.16	06.16

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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
2Q 2018 annual review: added HIM; removed requirements regarding contraindications; removed requirements for ruling out alternative of diagnoses; neonatal hypoglycemia: removed brain MRI and random GH measurement requirement; GHD, small for gestational age: removed requirements for open epiphyses, evidence of growth failure via appendix C, defined central nervous system pathology documented by MRI or CT; Prader-Willi syndrome: removed requirements for closed epiphyses, rGH will be titrated to maintain normal range IGF-1 level for age and sex matched controls, ruling out of contraindications, untreated severe sleep apnea, and active psychosis; CKD: removed requirements for open epiphyses, evidence of growth failure per appendix C, dx of CKD via Structural or functional abnormalities of the kidney for ≥ 3 months, GFR < 60 mL/min per 1.73 m^2 for ≥ 3 months, occurrence of both together of any duration, member does not have a functioning renal allograft; SBS: removed requirements for member's SBS therapeutic plan requires specialized nutritional support; changed approval duration from 3 months to 4 weeks; HIV-related wasting or cachexia: removed requirement for ruling out alternate causes of cachexia, unexplained loss of > 10% body weight from baseline, treatment with therapies other than rhGH have been suboptimal; added requirements for trial of appetite stimulants or anti-nausea tx as well as trial of testosterone and anabolic steroid in males; continued tx: removed documentation of adherence to therapy; removed examples of positive response criteria if not mandatory and objective; for Adult GHD: corrected peak GH level ≤ 5 µg/mL to ≤ 5	02.20.18	05.18

Reviews, Revisions, and Approvals	Date	P&T Approval Date
µg/L; aligned labs required for diagnosis with 2009 AACE guidelines; for Child/adolescent GHD: corrected peak GH level ≤ 10 µg/L to 10; GH use in children: added requirement for documentation of baseline height for initial approval.		
No significant changes: added 4 newly FDA-approved pediatric indications for Zomacton; no change to usage criteria as the policy already addressed use of Zomacton for these 4 indications.	09.26.18	
2Q 2019 annual review: added requirement for initial approval for use in children that member's bone age is ≤ 15 years if girl or ≤ 17 years if boy, consistent with existing requirement for continued therapy; references reviewed and updated.	02.06.19	05.19
1Q 2020 annual review: pediatric endocrinologist, open epiphyses, diagnostic criteria, auxology, and dosing added to all pediatric indications; post transplantation off-label use added to CKD; closed epiphyses added to adult GHD if younger than 18 years; dosing added to all adult indications; intravenous nutrition requirement add to SBS with gastroenterologist consultation; HIV-associated wasting - specialist added, GH treatment limited to one year per pivotal trial, failed trials edited to require two from two different therapeutic classes (Appendix B); references reviewed and updated.	11.19.19	02.20
HIM line of business removed from policy, HIM.PA.SP39 policy created.	12.05.19	
Auxology updates: correction for age and sex, GH Research Society GF options, and Appendix D added.	06.02.20	08.20
RT4: added FDA-approved GH analog Sogroya.	09.28.20	
Created local policy from corporate		11.20
Updated per IN Medicaid State Moratorium	12.2021	01.2022

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.

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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.