

Clinical Policy: Endocrine Agents: Growth Hormone

Reference Number: OH.PHAR.PPA.53

Effective Date: 01/01/2020

Last Review Date:

Line of Business: Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

GROWTH HORMONES

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
GENOTROPIN [®] cartridge, miniquick (somatropin) NORDITROPIN [®] cartridge, FlexPro, NordiFlex, vial (somatropin)	HUMATROPE [®] cartridge, vial (somatropin) NUTROPIN AQ [®] cartridge, Nuspin, vial (somatropin) NUTROPIN [®] vial (somatropin) OMNITROPE [®] cartridge, vial (somatropin) SAIZEN [®] cartridge, vial (somatropin) SEROSTIM [®] vial (somatropin) ZOMACTON [®] vial (somatropin)

FDA approved indication(s)

Genotropin is indicated for:

- Pediatric Patients: Treatment of children with growth failure due to growth hormone deficiency (GHD), Prader-Willi syndrome, Small for Gestational Age, Turner syndrome, and Idiopathic Short Stature
- Adult Patients: Treatment of adults with either childhood-onset or adult-onset GHD

Humatrope is indicated for:

- Pediatric Patients: Treatment of children with short stature or growth failure associated with growth hormone (GH) deficiency, Turner syndrome, idiopathic short stature (ISS), short stature homeobox-containing gene (SHOX) deficiency, and failure to catch up in height after small for gestational age birth
- Adult Patients: Treatment of adults with either childhood-onset or adult-onset GHD

Norditropin FlexPro is indicated for:

- Pediatric Patients: Treatment of children with growth failure due to GHD, short stature associated with Noonan syndrome, short stature associated with Turner syndrome, and short stature born small for gestational age with no catch-up growth by age 2 to 4 years, Idiopathic Short Stature (ISS), and growth failure due to Prader-Willi Syndrome
- Adult Patients: Treatment of adults with either childhood-onset or adult-onset GHD

Nutropin AQ NuSpin is indicated for:

- Pediatric Patients: Treatment of children with growth failure due to GHD, ISS, Turner syndrome (TS), and chronic kidney disease (CKD) up to the time of renal transplantation
- Adult Patients: Treatment of adults with either childhood-onset or adult-onset GHD

CLINICAL POLICY

Endocrine Agents: Growth Hormone

Omnitrope is indicated for:

- Pediatric Patients: Treatment of children with growth failure due to GHD, Prader-Willi Syndrome, Small for Gestational Age, TS, and ISS
- Adult Patients: Treatment of adults with either childhood-onset or adult-onset GHD

Saizen is indicated for:

- Pediatric Patients: Treatment of children with growth failure due to GHD
- Adult Patients: Treatment of adults with either childhood-onset or adult-onset 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:

- Pediatric Patients: Treatment of pediatric patients who have growth failure due to inadequate secretion of normal endogenous GH, short stature associated with TS, ISS, SHOX deficiency, and short stature born small for gestational age (SGA) with no catch-up growth by 2 years to 4 years
- Adult Patients: For replacement of endogenous GH in adults with GH deficiency

Zorbitive is indicate for:

- For the treatment of Short Bowel Syndrome (SBS) in patients receiving specialized nutritional support. Zorbitive therapy should be used in conjunction with optimal management of SBS.

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.

It is the policy of Buckeye Health Plan, an affiliate of Centene Corporation[®] that Endocrine Agents: Growth Hormone are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Growth Hormone Deficiency (GHD) in Children (must meet all):

1. Age \leq 18 years;
2. Documentation of low or low normal insulin-like growth factor-1 (IGF) -1 levels;
3. Failure of one preferred medication for \geq 90 days, unless member meets one of the following (a, b, or c):
 - a. allergy to medications not requiring prior approval;
 - b. contraindication to or drug interaction with medications not requiring prior approval;
 - c. history of unacceptable/toxic side effects to medications not requiring prior approval;
4. Prescribed by or in consultation with a pediatric endocrinologist or specialist appropriate for diagnosis;
5. Standard deviation (SD) of \geq 2.0 below mean height for chronological age;
6. No expanding intracranial lesion or tumor diagnosed;

CLINICAL POLICY

Endocrine Agents: Growth Hormone

7. Growth rate is one of the following (a, b, or c):
 - a. < five (5) centimeters per year;
 - b. < ten (10) centimeters per year in children under 3 years of age;
 - c. < ten (10) centimeters per year during puberty;
8. Two stimulation tests with peak levels ≤ 10 ng/mL;
9. Epiphyses must be open;
10. Member's bone age ≤ 15 -16 years in females and ≤ 16 -17 years in males.

Approval Duration: 180 days

B. Growth Retardation of Chronic Kidney Disease (CKD) in Children (must meet all):

1. Age ≤ 18 years;
2. Failure of one preferred medication for ≥ 90 days, unless member meets one of the following (a, b, or c):
 - a. allergy to medications not requiring prior approval;
 - b. contraindication to or drug interaction with medications not requiring prior approval;
 - c. history of unacceptable/toxic side effects to medications not requiring prior approval;
3. Prescribed by or in consultation with a pediatric endocrinologist or specialist appropriate for diagnosis;
4. Standard deviation (SD) of ≥ 2.0 below mean height for chronological age;
5. No expanding intracranial lesion or tumor diagnosed;
6. Growth rate < five (5) centimeters per year;
7. Irreversible renal insufficiency with a glomerular filtration rate (GFR) < 75 mL/min/1.73 m², but pre-renal transplant;
8. Member's bone age ≤ 14 -15 years in females and ≤ 15 -16 years in males;
9. Epiphyses must be open.

Approval Duration: 12 months

C. Genetic Diagnosis in Children (must meet all):

1. Diagnosis of one of the following (a, b, c, or d):
 - a. Krause-Kivlin Syndrome;
 - b. Turner Syndrome;
 - c. Prader-Willi Syndrome;
 - d. Noonan Syndrome;
2. Age ≤ 18 years;
3. Failure of one preferred medication for ≥ 90 days, unless member meets one of the following (a, b, or c):
 - a. allergy to medications not requiring prior approval;
 - b. contraindication to or drug interaction with medications not requiring prior approval;
 - c. history of unacceptable/toxic side effects to medications not requiring prior approval;
4. Prescribed by or in consultation with a pediatric endocrinologist or specialist appropriate for diagnosis;
5. Member's bone age ≤ 14 -15 years;
6. Epiphyses must be open;

CLINICAL POLICY

Endocrine Agents: Growth Hormone

7. Growth rate < five (5) centimeters per year.

Approval Duration: 12 months

D. Neurosecretory Growth Retardation in Children (must meet all):

1. Age \leq 18 years;
2. Failure of one preferred medication for \geq 90 days, unless member meets one of the following (a, b, or c):
 - a. allergy to medications not requiring prior approval;
 - b. contraindication to or drug interaction with medications not requiring prior approval;
 - c. history of unacceptable/toxic side effects to medications not requiring prior approval;
3. Prescribed by or in consultation with a pediatric endocrinologist or specialist appropriate for diagnosis;
4. Standard deviation (SD) of \geq 2.0 below mean height for chronological age;
5. No expanding intracranial lesion or tumor diagnosed;
6. Growth rate < five (5) centimeters per year;
7. Member's bone age \leq 14-15 years in females and \leq 15-16 years in males;
8. Epiphyses must be open;
9. Mixed or normal response to two stimulation tests in raising serum growth hormone above 10 ng/mL;

Approval duration: 180 days

E. Idiopathic Short Stature in Children (must meet all):

1. Age \leq 18 years;
2. Failure of one preferred medication for \geq 90 days, unless member meets one of the following (a, b, or c):
 - a. allergy to medications not requiring prior approval;
 - b. contraindication to or drug interaction with medications not requiring prior approval;
 - c. history of unacceptable/toxic side effects to medications not requiring prior approval;
3. Prescribed by or in consultation with a pediatric endocrinologist;
4. Standard deviation (SD) of \geq 2.25 below mean height for chronological age;
5. No expanding intracranial lesion or tumor diagnosed;
6. Growth rate < five (5) centimeters per year;
7. Member's bone age \leq 14-15 years in females and \leq 15-16 years in males;
8. Epiphyses must be open;
9. Mixed or normal response to two stimulation tests in raising serum growth hormone above 10 ng/mL;
10. Member is proportionally shorter than the predicted rate of growth from the parent's height.

Approval duration: 180 days

F. Small for Gestational Age (SGA) in Children (must meet all):

CLINICAL POLICY

Endocrine Agents: Growth Hormone

1. Age \leq 18 years;
2. Failure of one preferred medication for \geq 90 days, unless member meets one of the following (a, b, or c):
 - a. allergy to medications not requiring prior approval;
 - b. contraindication to or drug interaction with medications not requiring prior approval;
 - c. history of unacceptable/toxic side effects to medications not requiring prior approval;
3. Prescribed by or in consultation with a pediatric endocrinologist;
4. Documentation of birth weight or length \geq 2 standard deviations (SD) below the mean for gestational age;
5. Failure to manifest catch up growth before 2 years of age with documentation of the following:
 - a. height \geq 2 standard deviations (SD) below the mean for age and gender;
6. Documentation of evaluation of growth curves from birth.

Approval duration: 12 months

G. Adult Growth Hormone Deficiency (GHD) (must meet all):

1. Diagnosis of one of the following (a or b):
 - a. Adult GHD with childhood onset as evidenced by the following (i):
 - i. Documented continued deficiency confirmed by provocative testing;
 - b. Adult GHD with adult onset as evidenced by the following (ii) or (I):
 - i. GHD alone;
 - ii. multiple pituitary hormone deficiencies (i.e., hypopituitarism as a result of pituitary disease, surgery, hypothalamic disease, radiation therapy, or trauma);
2. Age \geq 18 years;
3. Prescribed by or in consultation with an endocrinologist;
4. Failure of one preferred medication for \geq 90 days, unless member meets one of the following (a, b, or c):
 - a. allergy to medications not requiring prior approval;
 - b. contraindication to or drug interaction with medications not requiring prior approval;
 - c. history of unacceptable/toxic side effects to medications not requiring prior approval;
5. Documentation of a negative response to an appropriate stimulation test (clonidine test is not acceptable for adults);
6. No evidence of malignancy or other contraindication;
7. Base-line evaluation of the following clinical indicators (a, b, c, d, e, f, and g):
 - a. Insulin-like growth factor-1 (IGF-1);
 - b. Fasting lipid profile;
 - c. BUN;
 - d. Fasting glucose;
 - e. Electrolyte levels;
 - f. Evaluation of any new osteoarthritis and joint pain;

CLINICAL POLICY

Endocrine Agents: Growth Hormone

- g. Bone density test;
- 8. If request is for a dose change, documentation of IGF-1 level;
- 9. Dose does not exceed one of the following (a or b):
 - a. < 0.025mg/kg daily, if age < 35 years;
 - b. < 0.0125 mg/kg daily, if age \geq 35 years.

Approval duration: 180 days

H. Wasting or Cachexia in HIV Patients (must meet all):

- 1. Diagnosis of HIV infection;
- 2. Age \geq 18 years;
- 3. Member is on concomitant anti-viral therapy for the treatment of HIV;
- 4. Involuntary weight loss of > 10% of body weight;
- 5. One of the following (a or b) unless contraindicated or clinically significant adverse effects are experienced:
 - a. If inadequate appetite, failure of megestrol acetate or dronabinol to simulate appetite;
 - b. If inadequate intake due to nausea, failure of \geq 1 preferred agent(s) for nausea;
- 6. Failure of a therapeutic trial of testosterone in combination with an anabolic steroid in males unless contraindicated or clinically significant adverse effects are experienced;
- 7. If request is for a non-preferred rhGH product, the preferred formulations are inappropriate (e.g., due to preservatives or dosing increment limitations) or member has a contraindication or experienced clinically significant adverse effects to preferred medications;
- 8. Dose does not exceed the maximum indicated in the prescribing information.

Approval duration: 3 months

I. Other diagnoses/indications

- 1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Growth Hormone Use in Children (must meet all):

- 1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
- 2. Member is responding positively to therapy as evidenced by improvement in health status (e.g., weight gain, improved body composition);
- 3. If request is for a dose increase, new dose does not exceed the maximum indicated in the prescribing information.

Approval duration: 12 months

B. Adult GHD or HIV-Related Cachexia (must meet all):

- 1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;

CLINICAL POLICY

Endocrine Agents: Growth Hormone

2. Member is responding positively to therapy;
3. If request is for Adult GHD, documentation by endocrinologist that discontinuing growth hormone would have a detrimental effect on body composition or other metabolic parameters;
4. If request is for a dose increase, new dose does not exceed the maximum indicated in the prescribing information.

Approval duration: 12 months

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.PMN.53 or evidence of coverage documents.

IV. 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

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
<i>Appetite stimulants</i>		
Megestrol (Megace [®])	400 - 800 mg PO daily (10 – 20 ml/day)	800 mg/day
Dronabinol (Marinol [®])	2.5 mg PO bid	20 mg/day
<i>Testosterone replacement products</i>		
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

CLINICAL POLICY

Endocrine Agents: Growth Hormone

Drug	Dosing Regimen	Dose Limit/Maximum Dose
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 steroid		
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 differ based on specific formulary used*

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
 - Genotropin, Genotropin Miniquick, Humatrope, Humatrope Combo Pack, Norditropin FlexPro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton: acute critical illness; children with Prader-Willi syndrome who are severely obese or have severe respiratory impairment (reports of sudden death); active malignancy; hypersensitivity; active proliferative or severe non-proliferative diabetic retinopathy; children with closed epiphyses
 - Zorbitive: acute critical illness; active malignancy; hypersensitivity; active proliferative or severe non-proliferative diabetic retinopathy
 - Serostim: acute critical illness; active malignancy; diabetic retinopathy; hypersensitivity
- Boxed warning(s): none reported

Appendix D: General Information

- In childhood cancer survivors who were treated with radiation to the brain/head for their first neoplasm and who developed subsequent GHD and were treated with somatotropin, an increased risk of a second neoplasm has been reported. Intracranial tumors, in particular meningiomas, were the most common of these second neoplasms. In adults, it is unknown whether there is any relationship between somatotropin replacement therapy and CNS tumor recurrence.

CLINICAL POLICY

Endocrine Agents: Growth Hormone

- Short stature/growth failure prior to rhGH therapy is evidenced by one of the following:
 - Height > 3 SD below the mean
 - 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
 - Height > 1.5 SD below midparental height
 - a) Boys: $(\text{father's height} + \text{mother's height} + 13 \text{ cm})/2$ or $(\text{Father's Height} + \text{Mother's Height} + 5 \text{ inches})/2$
 - b) Girls: $(\text{father's height} + \text{mother's height} - 13 \text{ cm})/2$ or $(\text{Father's Height} - 5 \text{ inches} + \text{Mother's Height}) / 2$
 - Height velocity > 2 SD below the mean over 1 year
 - Height velocity > 1.5 SD below the mean over 2 years
- The 2009 American Association of Clinical Endocrinologists (AACE) guidelines for clinical practice for growth hormone use in growth hormone-deficient adults and transition patients state that “there is no evidence that one GH product is more advantageous over the other, apart from differences in pen devices, dose increments and decrements, and whether or not the product requires refrigeration; therefore, we do not recommend the use of one commercial GH preparation over another.”
- Examples of positive response to therapy for cachexia in HIV patients include a 2% increase in body weight and/or body cell mass (BCM). Once BCM is normalized, therapy may be stopped and the patient may be monitored for wasting to reoccur.
 - Body cell mass (BCM): The total mass of all the cellular elements in the body which constitute all the metabolically active tissue of the body. The preferred method for assessing BCM depletion is bioelectrical impedance analysis (BIA) which can be performed with portable equipment in the office setting.
- GF-1 and IGFBP-3 levels should be interpreted against reference ranges that are standardized for sex and age (or better, by stage of sexual development, if available). The range varies with the assay used, and results should be interpreted against standards provided by the laboratory performing the test.
- Other than growth hormone (GH), pituitary hormones include the following:
 - ACTH: adrenocorticotrophic hormone
 - TSH: thyroid stimulating hormone
 - FSH: follicle stimulating hormone
 - LH: lutenizing hormone
 - PrL: Prolactin
 - Melatnocyte-stimulating hormone (MSH)
 - Oxytocin
 - ADH: Antidiuretic hormone

CLINICAL POLICY

Endocrine Agents: Growth Hormone

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Somatropin (Genotropin, Genotropin Miniquick, Humatrope, Humatrope Combo Pack, Norditropin Flexpro, Nutropin Aq Nuspin, Omnitrope, Saizen, Zomacton, Zorbtive)	Children and adolescents with GHD, small for gestational age, Turner syndrome, Prader- Willi syndrome, Noonan syndrome, SHOX deficiency, growth failure secondary to CKD, Adults with growth hormone deficiency, SBS	Refer to prescribing information (<i>Somatropin, rh-GH 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</i>)	Refer to prescribing information
Serostim	Wasting or Cachexia in HIV patients	<ul style="list-style-type: none"> • < 35 kg = 0.1 mg/kg SC QHS • 35 to 45 kg = 4 mg SC QHS • 45 kg to 55 kg = 5 mg SC QHS • > 55 kg = 6 mg SC QHS 	6 mg SC/day

VI. Product Availability

Drug	Availability
Genotropin lyophilized powder	Dual-chamber syringe: 5 mg, 12 mg
Genotropin Miniquick (without preservative)	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	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

CLINICAL POLICY

Endocrine Agents: Growth Hormone

Drug	Availability
Nutropin AQ NuSpin	Cartridge: 5 mg/2 mL Pen: 10 mg/2 mL, 20 mg/2 mL
Omnitrope	Cartridge: 5 mg/1.5 mL, 10 mg/1.5 mL Dual-chamber syringe: 5.8 mg
Saizen	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

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CLINICAL POLICY

Endocrine Agents: Growth Hormone

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Reviews, Revisions, and Approvals	Date	Approval Date
Policy created	10/19	

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.

CLINICAL POLICY

Endocrine Agents: Growth Hormone

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.

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Endocrine Agents: Growth Hormone

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