AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Recombinant Growth Hormone (rhGH)

Drug Requested: (Select **ONE** drug from below)

PREFERRED HGH	NON-PREFERRED HGH		
❑ **Omnitrope®**	❑ **Genotropin®**	❑ **Humatrope®**	❑ ***Ngenla™**
❑ **Norditropin®**	❑ **Nutropin®**	❑ **Nutropin AQ®**	❑ **Saizen®**
	❑ **Sogroya®**	❑ ***Skytrofa®**	❑ **Zomacton®**

***For use in members < 18 years of age**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 12 months

- ❑ Prescribed by or in consultation with an **endocrinologist** or **nephrologist**
- ❑ Provider has **COMPLETED** sections I, II and III below

Section I: Drug Criteria – Non-Preferred HGH agents require a trial of BOTH PREFERRED human growth hormone products within the previous 6 months for new starts unless non-formulary agent has FDA approved indication that is not approved for the formulary agent.

- ❑ Select **ONE** of the following:
  - ❑ Member tried and failed **BOTH PREFERRED** HGH products within the previous **6 months (verified by pharmacy paid claims; chart notes MUST be submitted for documentation)**
  - ❑ Member had adverse reaction to **BOTH PREFERRED** HGH products **(chart notes MUST be submitted for documentation)**

Section II: Growth Hormone Stimulation Test – Must be filled out for Adults and Children. Provider please note: Only 1 stimulation test is required for children with CNS pathology, MPHD, or proven genetic defect affecting the growth hormone axis. Growth hormone deficiency, including pituitary dwarfism, requires 2 stimulation tests.

- ❑ Provider has performed growth hormone stimulation test(s)
- ❑ Which of the following stimuli was utilized? **(check all that apply)**

❑ Insulin Induced Hypoglycemia	❑ Clonidine
❑ Arginine + GHRH	❑ Levodopa
❑ Arginine	❑ Propranolol
❑ Glucagon	❑ Other: _____

- ❑ Provider has submitted results of growth hormone stimulation test(s)

Stimuli	Test Date	Concentration	Peak GH Concentration

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- ❑ If no stimulation test was performed, please provide clinical rationale:

_____

_____

_____

_____

Section III: Diagnosis – Choose only ONE (1) of the following applicable diagnoses. Provider please note: Short Bowel Syndrome (SBS) and HIV-Wasting indications have their own separate prior authorization form and this form should NOT be utilized for those diagnoses.

For Adults:

- ❑ **ONE** of the following **MUST** be met:
  - ❑ Provider submits documentation to confirm members' growth hormone deficiency is the result of a documented **childhood** growth hormone deficiency
  - ❑ Member is 18 years of age or older and has a past medical history of **ONE** of the following:
    - ❑ Destructive Hypothalamic Disease
    - ❑ Destructive Pituitary Disease
    - ❑ Surgery
    - ❑ Trauma
    - ❑ Radiation Therapy

For Children:

- ❑ Provider has submitted **ALL** the following clinical documentation:
  - ❑ Gender: _____
  - ❑ Height (cm): _____
  - ❑ Weight (kg): _____
  - ❑ 12-month growth velocity: _____
  - ❑ Chronological Age: _____
  - ❑ Bone Age: _____
- ❑ Provider has submitted a growth chart showing pre-treatment heights and growth velocity
- ❑ **ONE** of the following auxologic evaluations **MUST** be met **UNLESS** not applicable for diagnosis:
  - ❑ Height is >2 SD below average for population mean height for age and sex **AND** height velocity measured over 1 year is >1 SD below the mean for chronological age
  - ❑ For children > 2 years old, there is a decrease in height SD of > 0.5 over one year **AND** one of the following:
    - ❑ Height velocity measured over 1 year is more than 2 SD below the mean for age and sex
    - ❑ Height velocity of >1.5 SD below the mean has been sustained over 2 years

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- ❑ Provider has selected **ONE** of the following indications for use and has submitted clinical documentation to support **ALL** corresponding clinical criteria:

❑ **Growth Hormone Deficiency (GHD) – Select ONE of the following:**

- ❑ CNS pathology **(check all that apply)**:
  - ❑ Hypoplasia of pituitary gland
  - ❑ Empty sella syndrome
  - ❑ Craniofacial developmental defects
  - ❑ Septo-optic dysplasia
- ❑ Multiple pituitary hormone deficiency (MPHD)
- ❑ Proven genetic defect affecting the growth hormone axis
- ❑ Growth hormone deficiency (e.g., pituitary dwarfism)
- ❑ Member has had appropriate imaging (MRI or CT Scan) of the brain with particular attention to the hypothalamic-pituitary region which excludes the possibility of a tumor
  - ❑ Provider has submitted a copy of imaging results

❑ **Cranial or Whole-Body Irradiation – submit chart notes to confirm past medical history**

❑ **Genetic Diseases**

- ❑ **Select ONE of the following:**
  - ❑ Turner's Syndrome
  - ❑ SHOX gene deletion
  - ❑ Noonan Syndrome
  - ❑ Prader-Willi Syndrome
- ❑ Member diagnosis has been established or confirmed by genetic testing
- ❑ Provider has submitted a copy of genetic testing results

❑ **Idiopathic Short Stature**

- ❑ Member's baseline height is less than the 3rd percentile for age and gender
- ❑ Member has open epiphyses
- ❑ Member does **NOT** have a constitutional delay of growth and puberty (CDGP)
- ❑ Member's height velocity is **ONE** of the following:
  - ❑ Growth rate < 4 cm per year for member's older than 5 years of age
  - ❑ Growth velocity < 10th percentile for member's age and gender

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❑ Panhypopituitarism

- ❑ Which of the following anterior pituitary hormones are absent? **(Check all that apply)**
  - ❑ Androcorticotropic Hormone (ACTH)
  - ❑ Antidiuretic Hormone (ADH)
  - ❑ Follicle Stimulating Hormone (FSH)
  - ❑ Luteinizing Hormone (LH)
  - ❑ Prolactin
  - ❑ Thyroid Stimulating Hormone (TSH)
- ❑ Provider has submitted chart notes or lab results to confirm hormone deficiency

❑ Small for Gestational Age

- ❑ Provider has submitted **ALL** the following clinical documentation:
  - ❑ Gestational age (in weeks) at time of birth: _____
  - ❑ Birth weight (kg): _____
  - ❑ Birth length (cm): _____
  - ❑ Height at age 2: _____
- ❑ Member's birth weight or length is two or more SD below the mean for gestational age
- ❑ Member has failed to reach catch-up growth by age 4, defined as height 2 or more SD below the mean for age and sex
- ❑ Provider attests other causes for short stature such as growth inhibiting medication, chronic disease, endocrine disorders, and emotional deprivation or syndromes have been ruled out

❑ Other Diagnosis (please specify below)

_____

_____

_____

_____

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Reauthorization: 12 months. Coverage for continuation of therapy requires meeting current initial use criteria and evaluation of response as shown by growth curve chart. Coverage for growth promotion will cease when the bony epiphyses have closed. Yearly reassessment for reauthorization of coverage is required.

For all members:

- ❑ Provider submits **ALL** the following clinical documentation:
  - ❑ Height velocity growth achieved during the previous 12 months of therapy: _____
  - ❑ Percentage of growth velocity from baseline during the 1st year of therapy: _____
  - ❑ Growth rate has remained above 2 cm per year
  - ❑ Expected adult height has not yet been reached
  - ❑ Member is compliant with therapy **(verified by pharmacy paid claims)**
  - ❑ **For children over 12 years of age,** provider submits documentation of an X-ray report with evidence that epiphyses have not yet closed (does not apply to children with prior documented hypopituitarism)

Medication being provided by Specialty Pharmacy – Proprium Rx

Not all drugs may be covered under every Plan.

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.****

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.*

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(Please ensure signature page is attached to form.)

Human growth hormone is FDA-approved for treatment of a limited number of conditions. The FDA has not approved the use of human growth hormone as therapy for anti-aging, longevity, cosmetic or performance enhancement. Federal law prohibits the dispensing of human growth hormone for non-approved purposes. A pharmacy's failure to comply with that law could result in significant criminal penalties to the pharmacy and its employees. Accordingly, a pharmacy may decline to dispense prescriptions for human growth hormone when written by physicians or other authorized prescribers who they believe may be involved in or affiliated with the fields of anti-aging, longevity, rejuvenation, cosmetic, performance enhancement or sports medicine.

Physician Must Complete this Section and Sign:

Prescriber Certification: I certify that this medication is not being prescribed for anti-aging, cosmetic, or athletic performance. I further certify human growth hormone is being prescribed for the medical condition noted above and is medically necessary.

Prescriber Signature: _____Date:

Attestation: I attest the information provided is true and accurate to the best of my knowledge. I understand that the Health Plan or insurer designees may perform a routine audit and request the medical information necessary to verify the accuracy of the information reported on this form.

Prescriber Signature: _____Date:

***Approved by Pharmacy and Therapeutics Committee:** ~~4/17/2014; 1/18/2018; 3/9/2022;~~ **8/16/2023**
UPDATED/REVISED/REFORMATTED: ~~4/22/2014; 5/16/2014; 10/31/2014; 5/21/2015; 12/27/2015; 12/16/2016; 2/23/2017; 8/13/2017; 11/24/2017; 2/21/2018; (Reformatted) 6/19/2019; 8/31/2020; 2/24/2022; 3/9/2022; 5/2/2022; 6/29/2022; 9/6/2023, 10/17/2023;~~ **8/21/2024**