HIGHMARK HEALTH OPTIONS

Updated: 11/2024
DMMA Approved: 12/2024

Request for Prior Authorization for Growth Hormone
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

All requests for Growth Hormone require a Prior Authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Growth Hormone products include Genotropin (somatropin), Humatrope (somatropin), Ngenla (somatrogon-ghla), Norditropin (somatropin), Nutropin/Nutropin AQ (somatropin), Omnitrope (somatropin), Saizen (somatropin), Serostim (somatropin), Skytrofa (lonapegsomatropin-tcgd), Sogroya (somapacitan), Zomacton (somatropin), Zorbtive (somatropin). New products with this classification will require the same documentation.

Growth Hormone Prior Authorization Criteria:

For all requests for Growth Hormone, all of the following criteria must be met:

- For Skytrofa, the member has had a 6-month trial of a short-acting growth hormone.
- For non-preferred agents, the member has had a trial and failure of preferred agent(s) or a clinically submitted reason for not having a trial of preferred agent(s).
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines.
- The member does not have any contraindications to growth hormone.

Coverage may be provided with a diagnosis of **pediatric growth hormone deficiency** and the following criteria is met:

- The medication is prescribed by or in consultation with an endocrinologist or neonatologist.
- Epiphyses are open.
- The member's height is greater than 2 standard deviations (SD) below the mean for age and gender
- ONE of the following:
    - 2 provocative simulation tests producing peak growth hormone concentrations <10 ng/ml
    - A low IGF-1 with ALL of the following:
        - Significant structural abnormality (such as pituitary stalk agenesis, empty stella, sellar or supra-sellar mass lesion, or ectopic posterior bright spot on an MRI or CT)
        - 1 provocative stimulation test producing peak growth hormone concentrations < 10 ng/ml
    - A low IGF-1 with panhypopituitarism (three or more documented pituitary hormone deficiencies other than growth hormone)
    - A low IGF-1 with ALL of the following:
        - Height is > 2.25 SD below the mean for age or > 2 SD below the midparenteral height percentile
        - Growth velocity is <25th percentile for bone age
        - A history of having passed (normal) growth hormone stimulation tests

- **Initial Duration of Approval**: 12 months
- **Reauthorization Criteria**
  - Epiphyses are open
  - A growth velocity of ≥ 2 cm/yr. (Provider must provide current documented height, and previously documented height from 12 months ago.)
  - Attestation that the member has not reached their expected final adult height
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of **pediatric growth failure due to chronic renal failure** and the following criteria is met:

- The medication is prescribed by or in consultation with an endocrinologist or neonatologist.
- Epiphyses are open.
- Member's current height is more than 2 standard deviations below the mean for age and gender.
- The member has not undergone a renal transplant.
- **Initial Duration of Approval**: 12 months
- **Reauthorization Criteria**
  - Epiphyses are open
  - A growth velocity of ≥ 2 cm/yr. (Provider must provide current documented height, and previously documented height from 12 months ago.)
  - Attestation that the member has not reached their expected final adult height:
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of **pediatric growth failure due to Noonan Syndrome or Turner Syndrome** and the following criteria is met:

- The medication is prescribed by or in consultation with an endocrinologist or neonatologist.
- Epiphyses are open.
- Member's current height is more than 2 standard deviations below the mean for age and gender.
- **Initial Duration of Approval**: 12 months
- **Reauthorization Criteria**
  - Epiphyses are open
  - A growth velocity of ≥ 2 cm/yr. (Provider must provide current documented height, and previously documented height from 12 months ago.)
  - Attestation that the member has not reached their expected final adult height
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of **pediatric growth failure due to Prader-Willi Syndrome** and the following criteria is met:

- The medication is prescribed by or in consultation with an endocrinologist.
- Epiphyses are open.
- Members under the age of 18 with ANY one of the following will not qualify for growth hormone:
  - Severely obese (BMI more than or equal to 30).
  - Severe respiratory impairment.

  - Upper airway obstruction or sleep apnea that is symptomatic..
- **Initial Duration of Approval**: 12 months
- **Reauthorization Criteria**
  - Presence of an improvement in linear growth or body composition (e.g., increase in lean body mass, lean/fat ratio, body weight, etc.).
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of **pediatric growth failure in children born small for gestational age (SGA),** and the following criteria is met:

- The medication is prescribed by or in consultation with an endocrinologist or neonatologist.
- Epiphyses are open.
- Member's current height is more than 2 standard deviations below the mean for age and gender.
- Member must meet ONE of the following requirements
  - Birth weight below the 10th percentile for the gestational age
  - Weight or length at birth is more than 2 standard deviations below the mean for gestational age.
- **Initial Duration of Approval**: 12 months
- **Reauthorization Criteria:**
  - Epiphyses are open
  - A growth velocity of ≥ 2 cm/yr. (Provider must provide current documented height, and previously documented height from 12 months ago.)
  - Attestation that the member has not reached their expected final adult height
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of **pediatric idiopathic short stature** and the following criteria is met:

- The medication is prescribed by or in consultation with an endocrinologist or neonatologist.
- Epiphyses are open
- Member's current height is below -2.25 standard deviations of the mean (i.e., the 1.2nd percentile), and a predicted adult height that is below the normal range; this corresponds to an adult height of less than 63 inches for males, and less than 59 inches for females.
- Other causes of short stature have been ruled out
- **Initial Duration of Approval**: 12 months
- **Reauthorization Criteria**
  - Epiphyses are open
  - A growth velocity of ≥ 2 cm/yr. (Provider must provide current documented height, and previously documented height from 12 months ago.)
  - Attestation that the member has not reached their expected final adult height
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of **Adult Growth Hormone Deficiency** and the following criteria is met:

- The medication is prescribed by or in consultation with an endocrinologist.
- Member is age 18 years and older OR any age with closed epiphyses.

- Member meets ONE of the following:
  - Member has a growth hormone stimulation test with peak growth hormone concentrations less than 5ng/mL as a result of ONE of the following:
    - Childhood onset growth hormone deficiency
    - Pituitary or Hypothalamic Disease
    - Surgery or Radiation Therapy
    - Trauma
  - Member has low IGF-1 and ONE of the following:
    - Panhypopituitarism (three or more documented pituitary hormone deficiencies other than growth hormone)
    - Structural abnormality of the hypothalamus or pituitary gland
- **Initial Duration of Approval**: 6 months
- **Reauthorization Criteria**
  - Presence of clinical benefit (e.g., increase in total lean body mass, increase in IGF-1, or increase in exercise capacity)
- **Reauthorization Duration of Approval:** 6 months

Coverage may be provided with a diagnosis of **Cachexia or Wasting associated with AIDS** and the following criteria is met:

- Prescribed medications is Serostim.
- Member must have diagnosis of HIV infection.
- Member must have a history of trial and failure, contraindication, or intolerance to at least ONE of the following conventional treatments:
  - Megestrol
  - Dronabinol*
- Prescriber must attest to ALL of the following:
  - Member must have involuntary weight loss of at least 10% from baseline premorbid weight or to a BMI <20 in the absence of a concurrent illness or medical condition other than HIV infection that would explain these findings.
  - Member must receive adequate caloric intake and nutritional counseling.
- **Initial Duration of Approval**: 12 weeks
- **Reauthorization Criteria:**
  - Presence of weight stabilization or weight gain. (Provider must provide pretreatment weight, and current weight.)
  - Duration of treatment will not exceed 48 weeks.
- **Reauthorization Duration of Approval:** up to 36 weeks

Coverage may be provided with a diagnosis of **Short Bowel Syndrome** and the following criteria is met:

- Prescribed medications is Zorbtive.
- Member is age 18 years or older.
- Member has malabsorption from the small intestine that is marked by diarrhea, malnutrition, and steatorrhea and that results from resection of the small intestine.
- Member has a small intestine <200 cm in length.
- Member has ONE of the following:

  - Member has an intact stomach and duodenum as well as ≥30% of functioning colon with at least 15 cm of intact jejunum and/or ileum
  - Member has an intact stomach and duodenum as well as <30% functioning colon with at least 90 cm intact jejunum and/or ileum.
- Member is receiving nutritional support.
- **Duration of Approval**: 4 weeks (maximum of 1 treatment course total)

* May require prior authorization

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

Drugs are authorized in generic form unless the branded product is on the preferred drug list or the prescriber has indicated in writing that the branded product is medically necessary. If only the branded product is on the preferred drug list, the generic form will be considered non-preferred and shall not require the prescriber to indicate in writing that the branded product is medically necessary.

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GROWTH HORMONE
PRIOR AUTHORIZATION FORM – PAGE 1 of 3

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX: (855) 476-4158**
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (844) 325-6251 Mon – Fri 8 am to 7 pm

PROVIDER INFORMATION	
Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION		
Member Name:	DOB:	
Health Options ID:	Member weight:	Height:

REQUESTED DRUG INFORMATION		
Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:	
Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No		

Billing Information
This medication will be billed: ☐ at a pharmacy **OR** ☐ medically, JCODE:_____
Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information	
Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)	
Diagnosis:	ICD Code:

For all members/diagnoses:

- Does the member have a contraindication to the requested growth hormone product? ☐ Yes ☐ No

For <u>pediatric</u> members only:

- Does the member have open epiphyses? ☐ Yes ☐ No

For Pediatric Growth Hormone Deficiency:

- Is the member's height greater than 2 standard deviations below the age related mean? ☐ Yes ☐ No
- Does the member have a diagnosis of failure to grow including (**one** of the following criteria):
  - Confirmation by 2 provocative stimulation tests producing peak growth hormone concentrations < 10 ng/mL? ☐ Yes ☐ No
  - A low insulin growth factor-1 (IGF-1) and significant structural abnormality affecting the pituitary and 1 provocative stimulation test producing peak growth hormone concentrations < 10 ng/mL? ☐ Yes ☐ No
  - A low IGF-1 with panhypopituitarism defined by at least 3 pituitary hormone deficiencies)? ☐ Yes ☐ No
  - A low IGF-1 and two normal/passed stimulation tests, has a height more than 2.25 standard deviations below the age related mean, and a growth velocity below the 25th percentile for bone age? ☐ Yes ☐ No

For Pediatric Growth Failure due to Chronic Kidney Disease (CKD):

- Is the member's current height more than 2 standard deviations below the mean for age and gender? ☐ Yes ☐ No
- Has the member undergone a renal transplant? ☐ Yes ☐ No

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GROWTH HORMONE
PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 2 OF 3

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MEMBER INFORMATION

Member Name:	DOB:	
Health Options ID:	Member weight:	Height:

MEDICAL HISTORY (Complete for ALL requests)

For growth failure due to Noonan Syndrome or Turner Syndrome:
- Is the member's current height more than 2 standard deviations below the mean for age and gender? ☐ Yes ☐ No

For growth failure due to Prader-Willi Syndrome:
- Does the member have any of the following?:
  - Severe obesity (BMI more than or equal to 30)? ☐ Yes ☐ No
  - Severe respiratory impairment? ☐ Yes ☐ No
  - A history or upper airway obstruction or sleep apnea? ☐ Yes ☐ No

For growth failure in Children Born Small for Gestational Age (SGA):
- Current height more than 2 standard deviations below the mean for age and gender? ☐ Yes ☐ No
- Birth weight below the 10th percentile for the gestational age? ☐ Yes ☐ No
- Weight or length at birth is more than 2 standard deviations below the mean for gestational age? ☐ Yes ☐ No

For Pediatric Idiopathic Short Stature:
- Is the member's current height below -2.25 standard deviations of the mean (the 1.2nd percentile)? ☐ Yes ☐ No
- Does the member have a predicted adult height that is below the normal range (adult height less than 63 inches for males and less than 59 inches for females)? ☐ Yes ☐ No
- Have other causes of short stature been ruled out? ☐ Yes ☐ No

For adult Growth Hormone Deficiency:
- Has the member undergone a growth hormone stimulation test with peak growth hormone concentrations less than 5 ng/mL resulting from childhood onset growth hormone deficiency, pituitary or hypothalamic disease, surgery or radiation therapy, or trauma? ☐ Yes ☐ No
- Does the member have a low IGF-1 and one of the following?: ☐ Yes ☐ No
  - ☐ Panhypopituitarism
  - ☐ Structural abnormality of the hypothalamus or pituitary gland

For Cachexia or Wasting Associated with AIDS:
- Does the member have a diagnosis of HIV infection? ☐ Yes ☐ No
- Has the member tried: Megestrol? ☐ Yes ☐ No
  Dronabinol? ☐ Yes ☐ No
- Has the member had an involuntary weight loss of ≥ 10% from baseline premorbid weight or to a BMI <20 in the absence of a concurrent illness or medical condition other than HIV infection that would explain these findings? ☐ Yes ☐ No
- Is the member receiving adequate caloric intake and nutritional counseling? ☐ Yes ☐ No

For Short Bowel Syndrome:
- Does the member have malabsorption from the small intestines that is marked by diarrhea, mal-nutrition, and steatorrhea that results from resection of the small intestine? ☐ Yes ☐ No
- Does the member have a small intestine <200 cm in length? ☐ Yes ☐ No
- Does the member have an intact stomach and duodenum as well as ≥30% of functioning colon with at least 15 cm of intact jejunum and/or ileum? ☐ Yes ☐ No
- Does the member have an intact stomach and duodenum as well as <30% functioning colon with at least 90 cm intact jejunum and/or ileum? ☐ Yes ☐ No
- Is the member receiving nutritional support? ☐ Yes ☐ No

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PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 3 OF 3

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MEMBER INFORMATION

Member Name:	DOB:	
Health Options ID:	Member weight:	Height:

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

For pediatric growth failure due to hormone deficiency, chronic renal failure, Noonan Syndrome, Turner Syndrome, children born small for gestational age, or pediatric idiopathic short stature:

- Does the member still have open epiphyses? ☐ Yes ☐ No
- Has the member experienced a growth velocity ≥ 2 cm/year? ☐ Yes ☐ No
  - Current height: _____ Date: _____
  - Last year height: _____ Date: _____
  - Has the member reached their expected final adult height? ☐ Yes ☐ No

For pediatric growth failure due to Prader-Willi Syndrome:

- Has the member improved in linear growth or body composition? (e.g., increase in lean body mass, lean/fat ratio, body weight) ☐ Yes ☐ No
  Please describe: _____

For adult growth hormone deficiency:

- Has the member exhibited clinical benefit (e.g., increase in total lean body mass, increase in IGF-1, or increase in exercise capacity)
  Please describe: _____

For cachexia or wasting associated with AIDs:

- Is there presence of weight stabilization or weight gain?
  - Current weight: _____ Date: _____
  - Pretreatment weight: _____ Date: _____

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date