

# Nebraska Medicaid Prior Authorization Process and Criteria – Growth Hormone (GH)

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## How Is Authorization Requested?

### Prescriber

**By Faxing Completed Form to Prime Therapeutics State Government Solutions LLC (Prime):** The prescriber must request authorization by faxing the patient's diagnosis and the other required information on a DHHS Fax Form. Requested data must be noted on the fax form. Data provided only on attachments is not acceptable. This form must be signed by the prescriber.

**Fax:** 1-866-759-4115

**(A fax request form is available at [nebraska.fhsc.com](https://nebraska.fhsc.com).)**

**OR**

**By Providing the Pharmacist with the Needed Information:** The prescriber may provide the needed information on a DHHS Fax Form to the pharmacist. The pharmacist will fax the information to Prime. Requested data must be noted on the fax form. Data provided only on attachments is not acceptable.

### Pharmacist

The dispensing pharmacist may use medical information provided by the prescriber to request authorization directly from the Prime Clinical Call Center by faxing the patient's diagnosis and the other required information on a DHHS Fax Form. Requested data must be noted on the fax form. Data provided only on attachments is not acceptable. The pharmacy must maintain this written information for the same length of time as the prescription record is required to be maintained by statute or regulation. Electronic storage/imaging shall meet this requirement.

**Fax:** 1-866-759-4115

**(A fax request form is available at [nebraska.fhsc.com](https://nebraska.fhsc.com).)**

## What Information Is Needed?

All requests for approval must be submitted in writing. Requests will only be accepted from the prescriber or dispensing pharmacy on the forms available as stated above. Preprinted forms from manufacturers or patient assistance agencies will not be accepted. If other insurance coverage exists, a copy of the approval/denial from the primary carrier(s) must accompany the request for prior authorization. All new Growth Hormone (GH) products approved subsequent to this bulletin shall be subject to these criteria.

## GH ≤ 18 Years of Age

Initial approval will be granted for 6 months.

Renewal may be granted for a period of up to 12 months, dependent upon compliance and response.

- Renewal may be denied for non-compliance, or
- Failure to demonstrate growth rate at least 2 cm/yr greater than pre-treatment rate, or
- Adult height has not been reached.

Growth hormone (GH) will only be approved for patients 18 years of age and younger, and when dispensed by an in-state provider. Coverage of GH must be approved prior to dispensing and the Department may deny coverage of any product dispensed prior to approval. Requests for renewal must include pharmacy dispensing/shipping records as well as documentation of compliance. Dispensed quantity may not exceed a 31-day supply. Current pharmacy program standards for early refill shall apply.

GH therapy for children will be authorized for certain FDA approved, medically necessary indications and will be limited to FDA approved doses. An evaluation by a Pediatric Endocrinologist or Pediatric Nephrologist is mandatory for initiation of GH treatment.

Requests for prior approval of GH therapy for children may be considered medically necessary for the following conditions:

- Documented endogenous GH deficiency
- Chronic Kidney Disease awaiting transplantation (CKD)
- Noonan's Syndrome
- Prader-Willi Syndrome (PWS)
- SHOX Deficiency
- Turner's Syndrome (TS)
- Panhypopituitarism
- Hypothalamic-pituitary disease

The following FDA approved indications for GH therapy are considered **not** medically necessary and requests will be denied:

- Patients born small for gestational age (SGA)
- Idiopathic short stature (ISS)

Requests for approval must include a current growth chart and results of all required diagnostic testing and will be reviewed based on the following criteria:

**All Requests for Children:**

- Evaluation by a pediatric endocrinologist or pediatric nephrologist
- Bone age < 16 years for males or < 14 years for females. Bone age not required for children chronologically age < 5 y/o
- Open epiphyses
- All causes for short stature, other than GH deficiency are ruled out.
- Thyroid levels must be within normal range or patient is receiving adequate replacement therapy.

**Growth Hormone Deficiency (GHD) Including Pituitary Dwarfism:**

- Physical stature < 3rd percentile.
- Bone age  $\geq 2$  standard deviations delayed with epiphyses indicating growth potential. (Not required for chronological age < 5 y/o)
- Family history (must include parents' heights).
- Growth velocity < 4cm/yr (ages 5–10 years).
- Exclusive of infants, 12 months old or less with hypoglycemia, two pharmaceutical provocative tests (or 1 test using 2 different agents) indicating response <10 ng/mL.
- Current height < midparental height:
  - Males:  $(\text{Father's height} + \text{Mother's height} + 13 \text{ cm}) \div 2$
  - Females:  $(\text{Mother's height} + \text{Father's height} - 13 \text{ cm}) \div 2$

**Pre-Transplant Chronic Kidney Disease (CKD):**

- Estimated GFR < 75 mL/min/1.73m<sup>2</sup> and significant growth impairment (height measurement below the third percentile for age)

**Diagnosis of Turner's Syndrome**

- Include diagnostic testing with request.

**Diagnosis of Prader-Willi Syndrome:**

- Include diagnostic testing with request.

**Diagnosis of Noonan's Syndrome:**

- Height is below the 5th percentile on growth charts for age and gender

### **Diagnosis of Short-Stature Homeobox (SHOX) Gene Deficiency:**

- Diagnosed by testing which documents presence of SHOX gene.

### **Panhypopituitarism:**

- Diagnosed by deficiency of 3 or more pituitary hormones, i.e., GH, ACTH, TSH, LH, FSH

**Hypothalamic-Pituitary Disease** of structure lesions/trauma to the pituitary including pituitary tumor, pituitary surgical damage, trauma, or cranial radiation:

- Has at least one documented low IGF-1 level below normal range for patient's age as per range on submitted lab document **and**
- Has deficiencies in one or more pituitary hormone (i.e., TSH, LH, FSH, ACTH, ADH).

## **GH ≥ 18 Years of Age**

Serostim and Zorbtive will only be approved for patients 18 years of age and older, and when dispensed by an in-state provider. Coverage must be approved prior to dispensing and the Department may deny coverage of any product dispensed prior to approval. Requests for renewal must include pharmacy dispensing/shipping records as well as documentation of compliance. Dispensed quantity may not exceed a 31-day supply. Current pharmacy program standards for early refill shall apply.

### **AIDS Wasting/Cachexia (Serostim)**

- Baseline weight loss of >10% over a 12-month period that can't be explained by a concurrent illness other than HIV infection
- Must be currently treated with antiretroviral agents
- Documentation of at least a 12-week trial and failure of dronabinol and/or megestrol
- **Initial** approval will be considered for 6 months, and **renewal** may be granted for a period of up to 12 months, dependent upon compliance and response to therapy

### **Short Bowel Syndrome (Zorbtive)**

- Must be receiving specialized nutritional support
- Must be prescribed by **or** in consultation with a gastroenterologist
- Approval will be considered for a maximum of 4 weeks per calendar year