I. Requirements for Prior Authorization of Growth Hormones

A. Prescriptions That Require Prior Authorization

All prescriptions for Growth Hormones, both preferred and non-preferred, must be prior authorized. See the Preferred Drug List (PDL) for the list of preferred and non-preferred Growth Hormones at: www.providersynergies.com/services/documents/PAM_PDL.pdf

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Growth Hormone, the determination of whether the requested prescription is medically necessary will take into account the following:

1. Whether the recipient has a history of therapeutic failure of the preferred Growth Hormones

AND

2. The dose of growth hormone requested is consistent with Food and Drug Administration (FDA) approved package labeling for diagnosis, age and weight

AND

3. The recipient has no contraindication to growth hormone

AND

4. Whether the growth hormone is being prescribed by a specialist such as a neonatologist (in the neonatal period) or endocrinologist

5. **For Neonates:** In addition to the guidelines listed in 1, 2, 3, and 4 above, whether the recipient has the following:

    a. A documented history of hypoglycemia with no metabolic disorder

    AND

b. Cortisol, Adrenocorticotropic Hormone (ACTH), Thyroid-Stimulating Hormone (TSH) and thyroxine levels which have been evaluated and treated if deficient

AND

c. Appropriate imaging (magnetic resonance imaging [MRI] or computed tomography [CT]) of the brain with particular attention to the hypothalamic pituitary region to exclude the possibility of a tumor

AND

d. A growth hormone level of < 20 ng/mL

FOR RENEWALS OF PRESCRIPTIONS FOR NEONATES: Requests for prior authorization of renewals of prescriptions for growth hormones that were previously approved will take into account whether the neonate has an Insulin-like growth factor (IGF-1) concentration in the normal range for age and gender.

6. **For Pediatrics**: In addition to the guidelines listed in 1, 2, 3, and 4 above, whether the recipient has Epiphyses that are confirmed as open for the following:
    - Recipients in Tanner stage greater than or equal to 3
    - Female recipients 12 years of age and older
    - Male recipients 14 years of age and older

    AND

    a. Has a diagnosis of pediatric growth hormone deficiency as documented by the following:

i. Height > 2 standard deviations (SD) below the age related mean
AND
ii. 2 provocative stimulation tests producing peak growth hormone concentrations < 10ng/ml

OR

iii. Significant structural abnormality such as pituitary stalk agenesis or empty stella with low insulin-like growth factor (IGF-1) and 1 provocative stimulation test producing peak growth hormone concentrations < 10 ng/ml

OR

iv. Panhypopituitarism (as defined by 3 or more deficient pituitary hormones in addition to growth hormone) with a low IGF-1

OR

v. A low IGF-1 with the following:
   a) Height is > 2.25 SD below the mean for age or > 2 SD below the midparenteral height percentile
   AND
   b) Growth velocity is <25th percentile for bone age
   AND
   c) A history of having passed growth hormone stimulation tests

AND

vi. Appropriate imaging (magnetic resonance imaging [MRI] or computed tomography [CT] of the brain was done with particular attention to the hypothalamic and pituitary regions to exclude the possibility of a tumor

AND

vii. The recipient's growth failure is not due to idiopathic short stature, familial short stature, or constitutional growth delay

AND

viii. Other causes for short stature have been excluded

OR

b. Has a diagnosis of pediatric growth failure, defined as height > 2 standard deviations (SD) below the age related mean, due to chronic renal failure and the recipient has not undergone a renal transplant

OR

c. Was born small for gestational age (SGA), defined as having a birth weight < 2500 g at a gestational age of 37 weeks and older, or weight or length at birth > 2 standard deviations below the mean for gestational age

AND

d. Failed to manifest catch up growth by 2 year of age, defined as height 2 or more standard deviations below the mean for age and gender

OR

e. Has growth failure defined as height > 2 standard deviations (SD) below the age related mean due to a diagnosis of Turner's Syndrome or Noonan's Syndrome, as documented by the following,

i. For Turner's Syndrome, genetic testing consistent with Turner's Syndrome

ii. For Noonan's Syndrome:

i. Clinical observation of the following key features:

1) Short stature
2) Abnormality of the cardiovascular system
3) Developmental delay of variable degree
4) Broad or webbed neck
5) Unusual chest shape with superior pectus carinatum, inferior pectus excavatum and apparently low-set nipples
6) Cryptorchidism in males
7) Characteristic facies
8) Coagulation defects or disordered bleeding
9) Neurologic abnormality such as seizure or hypotonia

10) Feeding difficulty
11) Ocular problems
12) Oral findings such as high arched palate, dental malocclusion or articulation difficulty
13) Peripheral lymphedema

OR

b) Patient has confirmed positive genetic testing for Noonan Syndrome.

OR

f. Has a diagnosis of Prader-Willi Syndrome, as documented by genetic testing consistent with Prader-Willi Syndrome, is receiving treatment for that Syndrome, and:

i. Has no symptoms of sleep apnea

OR

ii. Has a history of sleep apnea or symptoms consistent with sleep apnea and has been fully evaluated and treated

NOTE FOR RENEWALS OF PRESCRIPTIONS FOR PEDIATRICS:
Requests for prior authorization of renewals of prescriptions for growth hormones that were previously approved will take into account the following:

a. Whether the epiphyses are confirmed as open in:
   i. Recipients in Tanner stage greater than or equal to 3
   ii. Female recipients 12 years of age and older
   iii. Male recipients 14 years of age and older

AND

b. Whether the recipient demonstrates a growth response equal to or greater than 4.5 cm/yr (pre-pubertal growth rate) or equal to or greater than 2.5 cm/yr (post-pubertal growth rate)

AND

c. Whether the recipient has an IGF-1 concentration in the normal range for age and gender

AND

d. Whether the recipient has not reached their expected final adult height (defined as mid-parenteral height)

AND

e. For a diagnosis of Prader-Willi syndrome, whether the lean to fat body mass or growth velocity has improved

7. For recipients 18 years of age and older or recipients at any age with closed epiphyses, whether the recipient meets the guidelines listed in 1, 2, 3, and 4 above, and has a documented history of the following:

a. Adult growth hormone deficiency as a result of one of the following:

i. Childhood onset growth hormone deficiency
ii. Pituitary or hypothalamic disease
iii. Surgery or radiation therapy
iv. Trauma

AND

b. 2 stimulation tests (repeated in adulthood if the patient had testing as a child), showing growth hormone deficiency (defined as a peak growth hormone level of less than 5 ng/mL). Testing must use insulin to induce hypoglycemia as one of the agents (unless contraindicated) and the patient must have at least a one-month drug holiday from growth hormone if previously treated during childhood. Provocative testing with levodopa, arginine, clonidine, glucagon, or propranolol, will be accepted as the second agent and as a first agent in patients with a contraindication to insulin tolerance testing.

OR

c. Panhypopituitarism (as defined by 3 or more deficient pituitary hormones in addition to growth hormone) or a structural abnormality in the area of the hypothalamus or pituitary, with a low IGF-1 measured at least one month after stopping prior growth hormone therapy

AND

e. Currently receiving replacement therapy for any other pituitary hormone deficiencies that is consistent with current medical standards of practice

AND

f. For traumatic brain injury or subarachnoid hemorrhage recipients, stimulation testing obtained at least 12 months from the date of injury

FOR RENEWALS OF PRESCRIPTIONS FOR RECIPIENTS 18 YEAR OF AGE OR OLDER OR RECIPIENTS AT ANY AGE WITH CLOSED EPIPHYSES: Requests for prior authorization of renewals of prescriptions for growth hormones that were previously approved will take into account whether there is a presence of a clinical benefit of the growth hormone such as increase in total lean body mass, increase in exercise capacity or improved energy level. Additionally, authorization of renewal will take into account demonstration of compliance and a normal IGF-1.

8. For the treatment of **AIDS related cachexia**, whether the recipient meets the guidelines in 1, 2, 3, and 4 above and has all of the following:

   a. A diagnosis of wasting syndrome as defined by the following, and the wasting syndrome is not attributable to other causes such as depression, MAC, chronic infectious diarrhea, or malignancy (NOTE: Kaposi's sarcoma limited to the skin or mucous membranes is covered):

      i. Body mass index (BMI) of less than or equal to 18.5

      OR

      ii. BMI of Less than or equal to 25

      AND

      iii. An unintentional or unexplained weight loss of five percent in one month, seven and a half percent in three months, or ten percent in six months

   AND

   b. Despite a comprehensive AIDS treatment program that includes antiretrovirals, a history of inadequate response or intolerance to AIDS-related cachexia treatment options such as, but not limited to:

      i. Nutritional supplements that increase caloric and protein intake

      AND

ii. Steroid hormones such as megestrol

FOR RENEWALS OF PRESCRIPTIONS FOR AIDS RELATED CACHEXIA: Requests for prior authorization of renewals of prescriptions for growth hormones that were previously approved will take into account whether there is a presence of weight stabilization or increase.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above, to assess the medical necessity of the request for a prescription for a Growth Hormone. If the guidelines in Section B are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

D. Dose and Duration of Therapy

For Pediatrics and Adults - The Department will consider initial requests for prior authorization of a Growth Hormone for 6 months and requests for prior authorization of renewals of prescriptions for a Growth Hormone that were previously approved for 12 months.

For the treatment of AIDS related cachexia – The Department will consider request for prior authorization of a Growth Hormone for six (6) months. Requests for renewals of prescriptions for growth hormones that were previously approved will be considered but may not exceed a maximum of 48 weeks.

References:

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3. American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for Growth Hormone Use in Growth Hormone-Deficient Adults and Transition Patients – 2009 Update, Endocrine Practice. 2009;15(Suppl 2)
4. Management of tissue wasting in patients with HIV infection – UpToDate

5. Romano AA, et al. Noonan Syndrome: Clinical Features, Diagnosis, and Management Guidelines, Pediatrics. 2010;126:746-759
6. Abasi V. Growth and Normal Puberty, Pediatrics. 1998;102;507-511
7. Linear Growth Velocity, FamilyPracticeNotebook.com