

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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 Preferred Drug List (PDL) Attachment 1 in the PDL Chapter for the list of preferred and non-preferred Growth Hormones.

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. For Pediatrics:

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

AND

- b. Whether the recipient has a diagnosis of pediatric growth hormone deficiency with the following:

- i. Recipient's height is below the third (3rd) percentile for his/her age and gender related height
- ii. Recipient's growth velocity is subnormal (-2 to -3 standard deviations below the age related mean)
- iii. Recipient has delayed skeletal maturation (demonstrated through bone age estimated from an x-ray of the left wrist and hand) equal to or greater than 2 standard deviations below the age/gender related mean
- iv. Epiphyses is confirmed as open in recipients 10 years of age and older
- v. 2 provocative stim tests producing peak growth hormone concentrations < 10ng/ml

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- vi. 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
- c. Whether the recipient has a diagnosis of pediatric growth failure due to chronic renal failure and the recipient has not undergone a renal transplant
- d. Whether the recipient 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 below the third (3rd) percentile for gestational age

AND

Recipient fails to manifest catch up growth by 3 years of age, defined as height 2 or more standard deviations below the mean for age and sex

- e. Whether the recipient has a diagnosis of Turner's Syndrome or Noonan's Syndrome and the pediatric growth failure is due to that Syndrome
- f. Whether the recipient has a diagnosis of Prader-Willi Syndrome and is receiving treatment for that Syndrome
- g. Whether the recipient's growth failure is not due to idiopathic or familial short stature or constitutional delayed growth

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 is confirmed as open

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)

2. For Adults:

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

AND

- b. Whether the recipient has a diagnosis of 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

- c. Whether the recipient's growth hormone stimulation test demonstrates peak growth hormone concentrations of less than 5ng/ml

AND

- d. Whether the recipient is currently receiving adequate replacement therapy for any other pituitary hormone deficiencies

NOTE FOR RENEWALS OF PRESCRIPTIONS FOR ADULTS:

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 IGF-1 and IGFBP-3 levels, or increase in exercise capacity

- 3. For the treatment of AIDS related cachexia, whether the recipient meets all of the following:
 - a. The recipient has a diagnosis of wasting syndrome 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)

AND

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- b. The recipient has a history of inadequate response or intolerance to AIDS-related appetite stimulants.

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. Long Term Therapy

For Pediatrics - The Department of Public Welfare (Department) will consider requests for prior authorization of a Growth Hormone for 12 months. Prescriptions may be refilled as long as the refills do not exceed a six (6) month or five (5) refill supply, whichever comes first, from the time of the original filling of the prescription. See 55 Pa Code § 1121.53(c). Thus, if a recipient receives either a six (6) month or five (5) refill supply, whichever comes first, a new prescription, using the same prior authorization number will be required.

For Adults – The Department will consider requests for prior authorization of a Growth Hormone for six (6) 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.