PRIOR AUTHORIZATION: GROWTH HORMONE

Coverage

Recombinant human growth hormone therapy may be considered medically necessary for the following patients:

- Children (< 18 years) with growth hormone deficiency documented by an abnormal response of less than 10 ng/ml to two provocative stimulation tests
- Adults (≥18 years) with growth hormone deficiency documented by an abnormal response of less than 5 ng/ml on provocative stimulation testing
- Children with height less than 3rd percentile for chronologic age with chronic renal insufficiency
- Patients with Turner’s syndrome documented by chromosome analysis
- Patients with Prader-Willi syndrome documented by chromosome analysis
- Patients with AIDS wasting
- Patients with third degree burns

Recombinant human growth hormone therapy is considered not medically necessary for pediatric patients born small for gestational age (SGA) who fails to show catch-up growth by age 2 years.

Recombinant human growth hormone therapy is considered not medically necessary for pediatric patients with a height standard deviation score of -2.25 or below.

The efficacy of recombinant human growth hormone therapy has not been established by appropriate randomized clinical trials and its use, in the absence of documented growth hormone deficiency, is considered unproven and not medically necessary for the following conditions:

- Non-growth hormone deficient short stature, except for Turner’s syndrome
- Constitutional delay (lower than expected height percentiles compared with their target height percentiles and delayed skeletal maturation when growth velocities and rates of bone age advancement are normal)
- Growth hormone therapy in older adults
- Anabolic therapy, except for AIDS, provided to counteract acute or chronic catabolic illness (e.g., surgery outcomes, trauma, cancer, chronic hemodialysis) producing catabolic (protein wasting) changes in both adult and pediatric patients
- Glucocorticoid-induced growth failure
- Intrauterine growth retardation
- Short stature after renal transplantation
- Short stature due to Down’s or Noonan’s syndromes
- Treatment of alter body habitus (e.g., buffalo hump) associated with antiviral therapy in HIV-infected patients.
- Anabolic therapy to enhance body mass or strength for professional, recreational or social reasons
Discussion

No evidence-based criteria have been established for the laboratory diagnosis of growth hormone deficiency. The 2003 guidelines established by the American Associations of Clinical Endocrinologists comment on the complexity of establishing the diagnosis but propose no specific criteria. It is generally been considered that a peak growth hormone response of less than 10 ng/ml on each of two provocative stimulations tests is strongly suggestive of growth hormone deficiency in children, less than 18 years. Coverage for growth hormone is based on the premise that growth hormone is considered medically necessary as a physiologic replacement therapy for growth hormone deficiency and not medically necessary when used for short stature in the absence of growth hormone deficiency. Growth hormone therapy is typically discontinued when growth velocity is less than 2 cm per year, when epiphyseal fusion has occurred, or when height reaches the 5th percentile of adult height.

For adults, growth hormone deficiency is able to be documented by an abnormal response on two independent provocative stimulation tests. A peak response of less than 5 ng/ml is considered to be an abnormal response. It is thought that insulin tolerance testing is the most accurate and reliable of the testing strategies. Provocative testing may not be necessary for individuals with known central nervous system pathology including pituitary tumor, pituitary surgical damage, hypothalamic disease, irradiation, trauma, or reconfirmed childhood growth hormone deficiency.

Chronic renal insufficiency is considered to be creatinine clearance \( \leq 75 \text{ ml/min per } 1.73 \text{ m}^2 \). Growth hormone therapy is discontinued at the time of transplant or when the growth velocity is less than 2 cm per year, when epiphyseal fusion has occurred, or when height reaches the 5th percentile of adult height.

Turner’s syndrome defined as 45, XO genotype. Short stature is almost universal although growth hormone deficiency is rarely able to be documented. The randomized clinical trials documented an adult height advantage of 1.75 inches in the treatment group as compared to the control (untreated group) after a treatment period averaging 4.7 years. The clinical significance of this increase in height was not established.

Prader-Willi syndrome is a genetic disorder characterized by a microdeletion. The clinical presentation includes obesity, short stature, developmental disability and other signs. Growth hormone deficiency has been documented in almost able to be documented.

HIV-associated wasting is a diagnosis of exclusion when all other concurrent illness and HIV-associated malignancies have been ruled out. Generally coverage is limited to 12 weeks of therapy with follow-up of results.

Growth hormone therapy for burns is limited to patients with third degree burns.

Coverage for growth hormone is based on the premise that growth hormone is considered medically necessary as a replacement therapy for growth hormone deficiency, and is not medically necessary when used as treatment for short stature in the absence of growth hormone deficiency. This would include both those with short stature alone as well as those that are small for gestational age. The plan is not aware of an adverse health outcome associated with short stature in the absence of growth hormone deficiency. Based on a number of randomized placebo controlled clinical trials, the average net difference in height following 4.5 years of treatment ranged between the treatment group and the control patients ranged between 1.25 and 2.8 inches. Differences in functional impairment were not documented, either at the beginning or at the end of the studies. There is one random clinical trial that examined the behavior of children without documented growth hormone deficiency who were treated with growth hormone due to idiopathic short stature. After five years of growth hormone therapy, there was no significant difference in any self- or parental perception between the control and treatment groups. The conclusion drawn by the study is that there are no demonstrated psychosocial benefits of growth hormone therapy nor are there psychosocial ill effects of growth hormone treatment.
### Indication: Growth Hormone in Children

#### Initial Approval

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<tbody>
<tr>
<td>1.</td>
<td>Is the patient &lt; 18 years of age?</td>
<td><strong>If no, reference adult criteria</strong></td>
<td>Yes</td>
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<td>2.</td>
<td>Does the patient have the diagnosis Turner’s syndrome?</td>
<td><strong>If yes, skip to 6</strong></td>
<td>Yes</td>
<td>No</td>
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<td>3.</td>
<td>Does the patient have the diagnosis Prader-Willi syndrome?</td>
<td><strong>If yes, skip to #6</strong></td>
<td>Yes</td>
<td>No</td>
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<td>4.</td>
<td>Does the patient have the diagnosis chronic renal insufficiency or chronic renal failure?</td>
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<td>Yes</td>
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<td>5.</td>
<td>Does the patient have the diagnosis HIV-Associated Wasting Syndrome*?</td>
<td><strong>If yes, continue; if no, deny</strong></td>
<td>Yes</td>
<td>No</td>
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<td>* BMI &lt; 20 [(wt in lbs) ÷ (ht in inches)²] × 703 or 7.5% unintentional loss of weight over 6 months</td>
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<td>6.</td>
<td>Does the patient have a height that is more than 2.5 standard deviations below the mean for normal children of the same age? (less than the 5th percentile for age)</td>
<td><strong>If yes, continue; if no, deny</strong></td>
<td>Yes</td>
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<td>7.</td>
<td>Does the patient have a height more than 1.5 standard deviations below the mid-parental height?</td>
<td><strong>If yes, continue; if no, deny</strong></td>
<td>Yes</td>
<td>No</td>
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<td>8.</td>
<td>Does the patient have poor growth velocity (&lt; 2 cm per year)?</td>
<td><strong>If yes, continue; if no, deny</strong></td>
<td>Yes</td>
<td>No</td>
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<td>9.</td>
<td>Does the patient have a delayed bone age (bone age &gt; 6 months younger than chronological age)?</td>
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<td>Yes</td>
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<td>10.</td>
<td>Does the patient have closed or fused epiphyses?</td>
<td><strong>If yes, deny; if no and Turner’s—approve for 6 months</strong></td>
<td>Yes</td>
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<td><strong>if no and Prader-Willi—approve for 6 months</strong></td>
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<td><strong>if no and other indication, continue</strong></td>
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<td>11.</td>
<td>Has the patient failed at least two provocative growth hormone stimulation tests? (peak value &lt; 10 ng/ml)</td>
<td><strong>If yes, continue; if no, deny</strong></td>
<td>Yes</td>
<td>No</td>
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<td>12.</td>
<td>Has the patient been evaluated for other causes of growth failure? (e.g., thyroid deficiency)</td>
<td><strong>If yes, approve for 6 months; if no, deny</strong></td>
<td>Yes</td>
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#### Renewal Approval

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<tbody>
<tr>
<td>1.</td>
<td>Has the patient received at least 6 months of therapy:</td>
<td><strong>If yes, continue; if no, refer to “initial” criteria</strong></td>
<td>Yes</td>
<td>No</td>
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<td>2.</td>
<td>Does the patient have closed or fused epiphyses?</td>
<td><strong>If yes, deny; if no continue</strong></td>
<td>Yes</td>
<td>No</td>
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<td>3.</td>
<td>Has the patient’s height increased by more than 2 cm in the past 6 months?</td>
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<td>Yes</td>
<td>No</td>
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<td>4.</td>
<td>Has the patient’s growth velocity improved during the past 6 months?</td>
<td><strong>If yes, approve for 6 months; if no, consider denial</strong></td>
<td>Yes</td>
<td>No</td>
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Indication: *Growth Hormone in Adults*

** Initial Approval**

<table>
<thead>
<tr>
<th>1. Is the patient ≥ 18 years of age? <strong>If yes, continue; if no, reference children’s criteria</strong></th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>**2. Does the patient have adult-onset evidence of hypothalamic-pituitary disease, history of cranial irradiation, or documented childhood-onset growth hormone deficiency? <strong>If yes, continue; if no deny</strong></td>
<td>Yes</td>
<td>No</td>
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<tr>
<td><strong>3. Has the patient been assessed for other endocrine disorders?</strong> <em>(e.g., thyroid deficiency)</em> <strong>If yes, continue; if no, deny</strong></td>
<td>Yes</td>
<td>No</td>
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<tr>
<td><strong>4. Does the patient have the diagnosis HIV-Associated Wasting Syndrome?</strong> <strong>If yes, continue; if no deny</strong></td>
<td>Yes</td>
<td>No</td>
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<tr>
<td>* BMI &lt; 20 ( \left( \frac{\text{wt in lbs}}{\text{ht in inches}} \right)^2 \times 703 ) or 7.5% unintentional loss of weight over 6 months</td>
<td>Yes</td>
<td>No</td>
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<tr>
<td><strong>5. Has the patient failed at least two provocative growth hormone stimulation tests?</strong> <em>(failure is a peak &lt; 5 ng/ml RIA/polyclonal antibody; or &lt; 3.5 ng/ml IRMA/monoclonal antibody; or &lt; 3 ng/ml during hypoglycemia)</em> <strong>If yes, approve 6 months; if no, deny</strong></td>
<td>Yes</td>
<td>No</td>
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</table>

** Renewal Approval**

<table>
<thead>
<tr>
<th>1. Has the patient received at least 6 months of therapy? <strong>If yes, continue; if no, reference “initial” criteria</strong></th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td><strong>2. Has the patient been monitored for continuation of therapy (e.g., thyroid level, glucose level, lipid level, bioimpedance analysis and x-ray)</strong> <strong>If yes, continue; if no, deny</strong></td>
<td>Yes</td>
<td>No</td>
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<tr>
<td><strong>3. Has the treating practitioner evaluated the patient’s serum insulin-like growth factor 1 (IGF-1) to confirm appropriateness of therapy?</strong> <strong>If within age/sex adjusted normal range, approve for 6 months; if not done, deny</strong></td>
<td>Yes</td>
<td>No</td>
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*NOTE: the treating practitioner must monitor the insulin-like growth factor-1 every 6 months for continued approval.*
**Special Case: HIV-Associated Wasting Syndrome**

**Definition:**

AIDS is a chronic debilitating disease and is commonly associated with progressive loss of weight. While AIDS wasting syndrome shares many of the clinical features associated with the cachexia seen in cancer or sepsis, the pathophysiology of HIV-associated wasting syndrome is not well understood.

The time-honored definition of HIV-associated wasting, adopted by the Centers for Disease Control and Prevention is:

- Involuntary weight loss > 10% of baseline body weight
- Chronic diarrhea (2+ loose stools per day for more than 30 days) or chronic weakness and documented fever (for more than 30 days)
- No concurrent illness or condition other than HIV that could explain wasting (e.g., HIV-related cancer, tuberculosis, cryptosporidiosis, or other specific enteritis, etc.)

This definition is less useful now than when originally developed because wasting defined as above may be mimicked by lipoatrophy caused by highly active antiretroviral therapy (HAART) in which the loss is fat rather than lean body mass (LBM).

An alternative definition has been proposed as a result of the Consensus Development Panel Meeting Treatment guidelines for HIV-associated wasting, 2000:

- 10% unintentional weight loss over 12 months, or
- 5% body cell mass (BCM) loss over 6 months, or
- Body mass index (BMI) < 20 kg/m², or
- Male ($\geq$) body cell mass (BCM) < 35% of body weight AND BMI < 27 kg/m², or
- Female ($\geq$) body cell mass (BCM) < 23% of body weight AND BMI < 27 kg/m²

**NOTE:**

- Body weight (BW) = Fat + Lean body mass (LBM)
- Lean body mass (LBM) = Extracellular mass (EM) + Body cell mass (BCM)
- Body mass index (BMI) = [(Wt in lbs) / (Ht in inches)²] × 703

**Etiology:**

The causes are complex and multifaceted and include decreased oral intake, malabsorption, hormonal factors, cytokine effects, hypermetabolism and inefficient use of energy (futile metabolic cycles). Studies into the causes of AIDS often generate conflicting results. These are some general observations:

- The resting energy expenditure (REE) increases initially and has a tendency to increase further as the disease progresses. In the event of secondary infections, the REE does not significantly increase. Generally, as the disease progresses, the total energy expenditure (TEE) decreases as a result of the decrease in volitional energy expenditure. This decrease in TEE is not sufficient to counteract the decrease in caloric intake that is common in HIV progression.
- There is no convincing evidence that wasting regresses or decreases in prevalence with HAART but the fat redistribution in HAART-treated individuals may invalidate anthropometric measurements.
- As HIV disease progresses, secondary hypogonadism is commonly found. A low total testosterone is a good screening test in men. Although not universally accepted, hypogonadism may be more of a cause of wasting than an effect. Testosterone supplements help reverse loss of lean body mass (LBM) although the effects on body mass occur at higher concentrations of testosterone than seen in impotence.
- Increases in levels of some cytokine in HIV disease have been associated with wasting. To varying extents, tumor necrosis factor-alpha (TNF-α), interleukin-1, and interferon-alpha have been thought to be involved. While the mechanism of action is not well understood, attempts of treatment with cytokine inhibitors have been made.
- Low levels of cholesterol and albumin, and high levels of triglycerides are associated with wasting in AIDS. Hypertriglyceridemia is likely related to interferon-alpha and TNF-α although the significance of this is controversial. It’s also not known why this finding occurs in patients successfully treated with HAART.
- Alterations of protein and lipid metabolism are commonly found in AIDS patients, but studies have provided conflicting results as to the cause. It has been hypothesized, but not proven, that an anabolic block exists that prohibits accrual of lean body mass despite increased caloric intake. The explanation offered is futile metabolic cycles with uncontrolled cycling between triglycerides and fatty acid.
- In addition to negative energy or nitrogen balance, deficiency of micronutrients is common in AIDS wasting, including but not limited to vitamin B12, pyridoxine, zinc and selenium.

Management:

A prudent approach to management suggests that it may be more efficacious to approach weight loss in patients with HIV as a clinical problem rather than attempting to establish the diagnosis of AIDS wasting specifically. Although recognized as occurring in HIV/AIDS, few believe HIV-associated wasting is an AIDS-defining condition. There is very commonly a clinical explanation for the wasting phenomena. Even as weight loss is a harbinger of AIDS complications and comorbidities, reversal of weight loss is associated with improvement in physical function.

A rational approach to weight loss management would involve:

1. Identify weight loss and characterize changes in body composition, and
2. Identify reversible causes of weight loss, and
3. Treating specifically identified causes of weight loss.

It is expected that the HIV positive patient will have body weight obtained and charted at each medical visit and kept systematically. Body weight is a crude measurement and cannot discriminate between changes in different compartments. It is most useful as an indicator for more specific investigation into causes of weight loss.

Bioimpedance analysis (BIA) is the current standard of care for the identification and management of weight change including wasting seen in HIV affected individuals. The use of BIA provides highly reproducible estimates of body cell mass (BCM), the most stable estimate of a wasting diagnosis. In the absence of BIA measurement, requests for intensive management of HIV-associated wasting will be considered not medically necessary. For benefit coverage consideration, the establishment of HIV-associated wasting will be considered to be:

- Male (♂) body cell mass (BCM) < 35% of body weight AND BMI < 27 kg/m², or
- Female (♀) body cell mass (BCM) < 23% of body weight AND BMI < 27 kg/m²

Once a diagnosis of significant weight loss has been established, reversible and treatable causes must be ruled out. Generally, treatable causes of weight loss fall into hypermetabolism, malabsorption, inadequate caloric intake and/or hypogonadism. In conjunction with a meticulous history and physical, exclusion of concurrent opportunistic infections and a thorough assessment of caloric intake by a qualified nutritionist is essential.

In addition to treating an identified underlying cause (e.g., opportunistic infection, concurrent malignancy, iatrogenic, inadequate caloric intake, etc.) several adjunctive modalities are appropriate for consideration when the underlying cause has been addressed and a diagnosis of wasting remains:

- Appetite stimulants: megestrol acetate (Megace) has been studied although the evidence suggests that any weight gain is fat and not lean body mass. Corticosteroids, cyproheptadine and dronabinol or cannabis have also been studied and may improve appetite and mood but result in no significant weight gain and no improvement in health outcomes. They would be considered not medically necessary.
- Testosterone supplementation: the evidence suggests that physiologic replacement with IM testosterone, every three weeks for six months, in patients with decreased testosterone and AIDS wasting results in a significant increase in lean body mass. Transdermal testosterone has been evaluated via an appropriate placebo controlled random clinical trial and was not found to be significantly different from placebo and is considered not medically necessary and is not eligible for coverage. Currently testosterone is not indicated in women with HIV-associated wasting.

- Anabolic steroids: there is no evidence that these steroids are more effective than testosterone, experience is currently limited, this is not an FDA approved indication and anabolic steroids including oral oxandrolone (Oxandrin) and intramuscular nandrolone (Deca Durabolin) are considered not medically necessary and are not eligible for benefit coverage.

- Human growth hormone: there is evidence that subcutaneous recombinant human growth hormone (rhGH) for 12 weeks may result in fat loss, an increase in weight and an increase in lean body mass.

- Cytokine inhibition: there is evidence that treatment with thalidomide for 12 weeks may result in an increase in body weight although it is not certain whether the increase is primarily fat or lean body mass.

- Nutritional supplementation: in cases where restricted oral intake results in negative energy and nitrogen balance, oral formula supplements, enteral feeding through percutaneous gastrostomy or total parenteral nutrition may be indicated.

- Progressive resistance exercise: has a role in HIV-associated wasting and is synergistic with other interventions.

**Coverage Limitations:**

- The efficacy of anabolic steroids to treat and improve long-term health outcomes in HIV-associated wasting has not been established through appropriate random clinical trials and the use of anabolic steroids is considered experimental/investigational and/or unproven and is not eligible for benefit coverage.

- The efficacy of appetite stimulants to treat and improve long-term health outcomes in HIV-associated wasting has not been established through appropriate random clinical trials and the use of appetite stimulants is considered experimental/investigational and/or unproven and is not eligible for benefit coverage.

- The efficacy of tumor necrosis factor antagonists to treat and improve long-term health outcomes in HIV-associated wasting has not been established through appropriate random clinical trials and the use of cytokines or tumor necrosis factor antagonists is considered experimental/investigational and/or unproven and is not eligible for benefit coverage.
HIV-Associated Weight Loss

Unintentional weight loss in HIV/AIDS

Diagnostic evaluation to identify correctable or treatable confounding conditions

Underlying infection, malignancy, malabsorption, testosterone deficiency (male)

Inadequate nutrition

Treat and manage based on underlying causes(s)

Nutrition supplements including oral, enteral and parenteral

Monitor weight and treatment response

Persistent weight loss despite treatment

Consider: recombinent human growth hormone and/or testosterone replacement

Diagnosis Evaluation of Weight Loss:

- Nutritional intake—calories and nutrient composition
- Signs and symptoms of occult infection
- Signs and symptoms of HIV-associated malignancy
- Signs and symptoms of malabsorption
- Signs and symptoms of metabolic conditions
- HIV disease—CD4, viral load
- Height, weight, Body Mass Index
- Testosterone level in males
- Bioimpedenc Analysis (body cell mass)

Not Eligible for Benefit Coverage:

- Appetite stimulants
- Anabolic steroids
- Cytokines