

**Neighborhood Health Plan of Rhode Island
Prior Authorization Form
Human Growth Hormone - Omnitrope® (somatropin)
(Also, MD's office must call 877-456-6794 to receive Omnitrope Pen Device)**

If approval criteria are met Neighborhood Health Plan of RI will authorize coverage of Omnitrope Human Growth Hormone. Failure to fill out this form will result in a rejection of this medication at the pharmacy. Thank you for your assistance. Fax Number (866) 423-0945

PLEASE COMPLETE THE FOLLOWING SECTIONS:

Patient Name: _____ Member ID# : _____ Date of Request: _____

Date of Birth: ____/____/____ Pt. Weight in kg: _____

Provider Name: _____ Phone: _____

Provider Fax: _____ Contact Person in Office: _____

Indicate product being requested:

Omnitrope ®	<input type="checkbox"/>	
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Please give Directions for use: _____

Is the prescriber an endocrinologist? YES NO

INDICATIONS FOR USE

	YES	NO
1. Patient has growth failure associated with chronic renal insufficiency	<input type="checkbox"/>	<input type="checkbox"/>
a) Patient is in renal failure (glomerular filtration rate below 70ml/min/1.73m ²)	<input type="checkbox"/>	<input type="checkbox"/>
b) Patient is in good metabolic control and is able to maintain adequate nutritional intake	<input type="checkbox"/>	<input type="checkbox"/>
c) For patients in end stage renal disease with no hope for transplant will supplementation significantly improve quality of life?	<input type="checkbox"/>	<input type="checkbox"/>

2. Patient is diagnosed as small for gestational age (SGA)	<input type="checkbox"/>	<input type="checkbox"/>
a) Patient has a birth weight and/or length that is at least 2 SDS below the mean for gestational age	<input type="checkbox"/>	<input type="checkbox"/>
b) Patient's height remains SDS ≤ -2 by two years of age	<input type="checkbox"/>	<input type="checkbox"/>

3. Patient is diagnosed with idiopathic short stature	<input type="checkbox"/>	<input type="checkbox"/>
a) Pediatric patients demonstrate height SDS ≤ -2.25 and this is associated with growth rates that are unlikely to lead to adult height within the normal genetic potential	<input type="checkbox"/>	<input type="checkbox"/>
b) The prescribing physician is a <i>pediatric endocrinologist</i>	<input type="checkbox"/>	<input type="checkbox"/>
c) Diagnostic evaluation has excluded other causes of short stature	<input type="checkbox"/>	<input type="checkbox"/>

4. Patient is diagnosed with growth failure in a child due to lack of growth hormone secretion	<input type="checkbox"/>	<input type="checkbox"/>
a) Patient has abnormally low values (<10ng/mL) of serum GH on two provocative tests	<input type="checkbox"/>	<input type="checkbox"/>
b) Patient's height is > 2.0 standard deviations below the mean height for normal children of the same age	<input type="checkbox"/>	<input type="checkbox"/>
c) Conditions that depress GH secretion have been ruled out in this patient (e.g. hypothyroidism, chronic nonendocrine disease, etc.)	<input type="checkbox"/>	<input type="checkbox"/>

5. Patient has been diagnosed with Turner's Syndrome	<input type="checkbox"/>	<input type="checkbox"/>
a) Karyotype or fibroblast studies reveal chromosomal information consistent with the disease	<input type="checkbox"/>	<input type="checkbox"/>

YES NO

6. Patient has been diagnosed with Prader-Willi Syndrome (PWS)	<input type="checkbox"/>	<input type="checkbox"/>
a) There is chromosomal information consistent with the disease	<input type="checkbox"/>	<input type="checkbox"/>

7. Patient has been diagnosed with AIDS wasting or cachexia	<input type="checkbox"/>	<input type="checkbox"/>
a) Drug requested must be Serostim®	<input type="checkbox"/>	<input type="checkbox"/>
b) Patient must have had a previous trial with megestrol acetate (Megace®)	<input type="checkbox"/>	<input type="checkbox"/>
c) Patient must be taking concomitant antiviral therapy	<input type="checkbox"/>	<input type="checkbox"/>

8. Patient has been diagnosed with somatropin deficiency in adults	<input type="checkbox"/>	<input type="checkbox"/>
a) Patient has a biochemical diagnosis of somatropin deficiency syndrome, by means of a substandard response to a standard growth hormone stimulation test. This will not be required in patients with a known permanent pituitary dysfunction (i.e. trauma or surgery).	<input type="checkbox"/>	<input type="checkbox"/>
b) Adult onset patients have somatropin deficiency as a result of pituitary disease, hypothalamic disease, surgery, trauma, or radiation therapy	<input type="checkbox"/>	<input type="checkbox"/>
c) Adult patients with onset as children continue to require replacement for normal homeostasis rather than growth promotion	<input type="checkbox"/>	<input type="checkbox"/>

If this is a renewal, review of the past 6 months demonstrates:

	YES	NO
Pediatric patients demonstrate a continued growth rate of greater than 2cm per year	<input type="checkbox"/>	<input type="checkbox"/>
For pediatric patients who are small for gestational age, the total treatment duration will not exceed a 2 year period	<input type="checkbox"/>	<input type="checkbox"/>
There is no indication of epiphyseal closure in pediatric patients being treated for growth promotion	<input type="checkbox"/>	<input type="checkbox"/>
For pediatric patients who have recently received a renal transplant, supplementation should continue until achievement of final adult height or epiphyseal closure	<input type="checkbox"/>	<input type="checkbox"/>
Patient continues to need growth hormone for physiological homeostasis	<input type="checkbox"/>	<input type="checkbox"/>

CONTRAINDICATIONS FOR USE

	YES	NO
1. Patient does not meet criteria for approval	<input type="checkbox"/>	<input type="checkbox"/>
2. Patient has closed epiphyses.	<input type="checkbox"/>	<input type="checkbox"/>
3. Patient has sensitivity to benzyl alcohol.	<input type="checkbox"/>	<input type="checkbox"/>
4. Patient has evidence of tumor activity or active neoplasia.	<input type="checkbox"/>	<input type="checkbox"/>
5. Patient has sensitivity to m-cresol or glycerin and is receiving Humatrope®.	<input type="checkbox"/>	<input type="checkbox"/>

If patient meets criteria: Also, MD's office must call 877-456-6794 to receive Omnitrope Pen Device

- **Initial approval: 6 months**
- **Renewal approval period: 6 months**

Information given on this form is accurate as of this date.

Prescriber's signature and NPI

Date

References

1. Olin BR, ed. Drug Facts and Comparisons (Updated Monthly). Facts and Comparisons. St. Louis, 2003.
2. AACE clinical practice guidelines for growth hormone use in adults and children-2003 update. *Endocrine Practice* 2003;9(1):64-76.
3. Guidelines for the use of growth hormone in children with short stature: a report by the Drug and Therapeutics Committee of the Lawson Wilkins Pediatric Endocrine Society. *J Pediatr* 1995;127:857-67.
4. Vance ML, Mauras N. Growth hormone therapy in adults and children. *N Engl J Med* 1999;Oct 14:1206-16.
5. Haffner D, Schaefer F, Nissel R, et al. Effect of growth hormone treatment on the adult height of children with chronic renal failure. *N Engl J Med* 2000; 343:923-30.
6. Lee PA, Kendig JW, Kerrigan JR. Persistent short stature, other potential outcomes, and the effect of growth hormone treatment in children who are born small for gestational age. *Pediatrics* 2003;112:150-162.