

**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

- Olin BR, ed. Drug Facts and Comparisons (Updated Monthly). Facts and Comparisons. St. Louis, 2003.
- AACE clinical practice guidelines for growth hormone use in adults and children-2003 update. *Endocrine Practice* 2003;9(1):64-76.
- 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.
- Vance ML, Mauras N. Growth hormone therapy in adults and children. *N Engl J Med* 1999;Oct 14:1206-16.
- 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.
- 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.