

## Drug Name: Nutropin NuSpin® (somatropin) Last Revision Date: 06-2016 Date: 09-2017

Drug Name:	Nutropin NuSpin® (somatropin)
Required Medical Information:	Patient's diagnosis is one of the following:
	• Growth Hormone Deficiency (pediatrics):
	<ul> <li>Patient is being treated under the care of a pediatric endocrinologist; <i>and</i></li> <li>Patient has abnormally low values (&lt; 10 ng/mL) of serum GH on two provocative tests; <i>and</i></li> <li>Patient height is greater than 2 standard deviations below the mean height for normal children of the same age; <i>and</i></li> <li>There is no evidence of epiphyseal closure after careful review; <i>and</i></li> <li>Patient has been evaluated for alternative diagnoses that suppress growth hormone secretion (e.g. hypothyroidism, chronic non-endocrine disease, etc.); <i>and</i></li> <li>With growth hormone therapy, patient demonstrates a continued growth rate of greater than 4 cm per year.</li> </ul>
	<ul> <li>Small for gestational age (pediatrics): <ul> <li>Patient is being treated under the care of a pediatric endocrinologist; and</li> <li>Patient has a birth weight and/or length that is at least 2 standard deviations below the mean for gestational age whose height remains less than or equal to 2 standards deviations below the mean by two years of age; and</li> <li>Total treatment duration will not exceed 2 years.</li> </ul> </li> </ul>
	• Prader-Willi Syndrome (PWS) or Turner's Syndrome
	(pediatrics):
	• Patient is being treated under the care of a pediatric endocrinologist; <i>and</i>
	• Chromosomal information is consistent with the disease.
	• Idiopathic Short Stature (IDSS) (pediatrics):
	• Patient is being treated under the care of a pediatric endocrinologist; <i>and</i>
	<ul> <li>Patient has been evaluated for all other diagnoses that may cause short stature and demonstrates a predicted final height to be less than 3 standard deviations (which is</li> </ul>



<ul><li>year; <i>and</i></li><li>There is no evidence of epiphyseal closure after careful</li></ul>
<ul> <li>on stable immunosuppression; <i>and</i></li> <li>Patient has a post-transplant rate of less than 3 cm per user; and</li> </ul>
• Pediatric patient with recent renal transplant is maintained
• Growth failure associated with chronic renal insufficiency in pediatric patients post-renal transplant:
<ul> <li>Pediatric patient who has, prior to growth hormone treatment, demonstrated a growth rate of no less than 3 cm per year.</li> </ul>
<ul> <li>support growth; <i>and</i></li> <li>Growth hormone will significantly improve quality of life for patient who is in end stage renal disease and is awaiting renal transplant; <i>and</i></li> </ul>
<ul> <li>Patient has chronic kidney disease (CKD stage 4 or 5); and</li> <li>Patient is in adequate metabolic control (PTH no less than 4 times normal, Ca 8.5-10.5 mg/dL, Phos 4.0-6.0 mg/dL) <u>AND</u> can maintain caloric intake needed to</li> </ul>
• Growth failure associated with chronic renal insufficiency:
<ul> <li>intolerance and/or inadequate response; and</li> <li>Patient is adherent to concomitant antiviral therapy.</li> </ul>
<ul> <li>AIDS wasting or cachexia:         <ul> <li>Patient has failed a trial of megestrol acetate (Megace®) at an adequate dose and for an appropriate duration due to</li> </ul> </li> </ul>
<ul> <li>Growth Hormone Deficiency (adults):         <ul> <li>Patient is under the care of an endocrinologist; and</li> <li>Patient has documented abnormally low values (less than 10 ng/mL) of serum GH on two provocative tests; and</li> <li>Patient is being treated for somatopin deficiency as a result of a pituitary disease, hypothalamic disease, surgery, trauma, radiation therapy, <u>OR</u> adult with child-onset growth hormone deficiency continues to require therapy for normal homeostasis.</li> </ul> </li> </ul>
<ul><li>associated with growth rates that are unlikely to lead to adult height within the normal genetic potential); <i>and</i></li><li>Patient's current bone age is 10 to 14.</li></ul>