



**BlueCross
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Federal Employee Program.

PEDIATRIC GROWTH HORMONES

Genotropin, Humatrope, Ngenla, **Norditropin**, Omnitrope, Saizen, Sogroya, Skytrofa, Zomacton (aka. Tev-Tropin)

Preferred product: Norditropin

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Somatropin is a synthetically manufactured genetic copy of natural human growth hormone produced in the pituitary gland. It has the same effect as natural human growth hormone made in the body. Growth hormone (GH) contributes to overall bone, muscle, and organ growth and development in humans. Children with inadequate production of growth hormone, which can be due to various diseases and reasons, require growth hormone replacement in order to complete their development from childhood to adulthood (1-2).

Somatropin, commonly referred to growth hormone, is currently marketed for use in children under the following brands: Genotropin, Humatrope, Norditropin, Omnitrope, Saizen, Skytrofa, and Zomacton (formerly known as Tev-Tropin). Ngenla contains somatrogon, a synthetic growth hormone. Skytrofa is a pegylated version of somatropin allowing for once-weekly subcutaneous dosing (3-11).

Use of any growth hormone in children can cause a number of potentially serious adverse effects; therefore, regular and routine monitoring is required. Sometimes treatment may need to be permanently stopped. These adverse effects include the development of impaired glucose tolerance and diabetes mellitus, upper airway obstruction and sleep apnea in patients with Prader-Willi syndrome, progression or recurrence of tumors in patients with preexisting tumors, intracranial hypertension, the worsening of hypothyroidism, the worsening of pre-existing scoliosis, and pancreatitis (1-2).

Regulatory Status

FDA-approved indications: Pediatric growth hormone is indicated for: growth hormone deficiency (GHD)/insufficiency; growth failure secondary to chronic renal insufficiency pre-transplantation, Noonan Syndrome, Prader-Willi Syndrome, Turner Syndrome or SHOX (short stature homeobox-containing gene) deficiency; small for gestational age (SGA) for children who have not reached a normal height range by age 2 to 4 years or idiopathic short stature (ISS) (3-9).



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Skytrofa is indicated for the treatment of pediatric patients 1 year and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous growth hormone (10).

Ngenla is indicated for the treatment of pediatric patients 3 years and older who have growth failure due to inadequate secretion of endogenous growth hormone (11).

Although the FDA-labeled indications vary for the growth hormone products, guidelines address all somatropin products collectively with the exception of Skytrofa (1-2).

Summary

Pituitary growth hormone is a peptide that exerts anabolic effects on target tissues. Growth hormone (GH) secretion is regulated by a balance between growth hormone–releasing hormone (GHRH) and growth hormone-inhibiting (somatostatin) factors. Other growth hormone–releasing peptides (GHRPs) are known to stimulate GH. Receptors for the GHRPs have been identified, and the natural ligand for these receptors has been determined to be ghrelin (1-2).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of pediatric growth hormones while maintaining optimal therapeutic outcomes.

References

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