Custom Criteria for
BlueCross Blue Shield of Rhode Island Commercial

catamaran™

HUMAN GROWTH HORMONE

GPI CODING:

Genotropin, Tev-Tropin, Humatrope, Nutropin, Omnitrope	301000200021**
Norditropin, Nutropin AQ, Omnitrope	301000200020**
Serostim 4mg Inj	30100020102118
Serostim 5mg Inj	30100020102121
Serostim 6mg Inj	30100020102125
Saizen 8.8mg inj	30100020102130
Saizen 5 mg inj	30100020102120

DESCRIPTION:

Product	Generic Name	FDA Approved Indication(s)
Preferred Agent		
Nutropin® / Nutropin AQ®	somatropin	Pediatric GHD, CRI, TS, ISS, adult GHD
Non-preferred Agents		
Genotropin®	somatropin	Pediatric GHD, PWS, SGA, TS, ISS, adult GHD
Humatrope®	somatropin	Pediatric GHD, TS, ISS, SGA, SHOXD, adult GHD
Norditropin®	somatropin	Pediatric GHD, NS, TS, SGA, adult GHD
Omnitrope®	somatropin	Pediatric GHD, PWS, SGA, ISS, adult GHD
Saizen®	somatropin	Pediatric GHD, adult GHD
Serostim®	somatropin	HIV-associated wasting
Tev-Tropin®	somatropin	Pediatric GHD
Zorbtive®	somatropin	SBS patients receiving nutritional support

Abbreviations: CRI = chronic renal insufficiency; FDA = Food and Drug Administration; GHD = growth hormone deficiency; HIV = human immunodeficiency virus; ISS = idiopathic short stature; NS = Noonan syndrome; PWS = Prader-Willi syndrome; SBS = short bowel syndrome; SGA = small for gestational age; SHOXD = short stature homeobox-containing gene deficiency; TS = Turner syndrome.

APPROVAL DURATION:

Approval duration: 1 year
Quantity Limit: 28 injections per 28 days

CRITERIA FOR GROWTH HORMONE

A trial of Nutropin/Nutropin AQ is required for requests for non-preferred growth hormones with the exception of Serostim and Zorbtive

I. Children under the age of 18 with one of the following:
   A. Documented growth hormone deficiency (GHD) that meets one of the following criteria:

i. Diminished peak serum GH response (<10 ng/ml) to at least 1 provocative stimuli (arginine, clonidine, glucagons, insulin induced hypoglycemia, l-dopa, or propranolol) **OR**
ii. Neonates with hypoglycemia and clinical and hormone evidence of hypopituitarism and low GH (at least one GH stimulation test is subnormal) **OR**
iii. Documented presence of at least 3 other pituitary hormone deficiencies (GH stimulation tests are not required in this subgroup of patients)

B. Growth hormone treatment may be considered RECONSTRUCTIVE in nature and approved if the patient meets one of the following conditions:
   i. Estimated final adult height, based on bone age, of > 2.5 standard deviations (SD) below the mean with a condition known to be responsive to GH therapy, including but not limited to:
      1. chronic renal insufficiency, idiopathic short stature, Prader-Willi syndrome, Noonan syndrome, Turner syndrome, partial growth hormone deficiency, neurosecretory dysfunction
      2. Children who are born small for gestational age (SGA) defined as a child was born SGA, defined as birth weight or length 2 or more SD below the mean for gestational age (infants with intrauterine growth restriction or Russell-Silver syndrome resulting in SGA are included in this category) AND child fails to manifest catch up growth by age 2 years, defined as height 2 or more SD below the mean for age and sex AND other causes for short stature such as growth inhibiting medication, chronic disease, endocrine disorders, emotional deprivation or syndromes (except for Russell-Silver syndrome) have been ruled out.
      3. Other etiologies of short stature not associated with GHD

II. Growth hormone therapy in adults with one of the following:
   A. Adult GHD or somatropin deficiency syndrome who meet the following conditions:
      i. Documented GHD in childhood OR
      ii. Documented hypopituitarism as a result of pituitary disease, hypothalamic disease, surgery, radiation therapy, or trauma
      iii. The diagnosis of GHD must be confirmed, or reconfirmed, by any of the following:
         1. A documented subnormal response in adults, defined as serum GH level <5 ng/mL when measured by RIA (polyclonal antibody) or <2.5 ng/mL when measured by IRMA (monoclonal antibody), to 2 standard GH stimulation tests OR
         2. Subnormal response to 2 stimulation tests for adults with documented hypothalamic or pituitary disease and one or more additional pituitary hormone deficits OR
         3. Documented presence of at least 3 other pituitary hormone deficiencies (GH stimulation tests are not required in this subgroup of patients)

III. HIV patients with AIDS wasting syndrome
   A. Patient has HIV with AIDS wasting syndrome, defined as a greater than 10% of baseline weight loss that cannot be explained by a concurrent illness other than HIV infection
   B. Patients treated with GH for AIDS wasting must simultaneously be treated with antiviral therapy

IV. Continuation and termination of therapy

A. Continuation of GH therapy may be approved in children who previously met criteria for GHD or reconstructive treatment when the following are met:
    i. Review should occur on an annual basis for all conditions; AND
    ii. A doubling of pre-treatment growth rate or an increase in pre-treatment growth rate of 3 cm/year or more seen in the first year of therapy (does not apply to children with prior documented hypopituitarism); AND
    iii. For therapy continuing past the first year, growth rate remains above 2.5 cm/year (does not apply to children with prior documented hypopituitarism); AND
    iv. For children over age ten: an X-ray report with evidence that epiphyses have not yet closed (does not apply to children with prior documented hypopituitarism).
    v. GH therapy used for reconstruction should be terminated when any of the following criteria are met:
        1. Bone age = 16 years (male) or = 14 years (female) is reached OR
        2. Epiphyseal fusion has occurred OR
        3. "Mid-parental height" is achieved. Mid-parental height = (father's height + mother's height) divided by 2, plus 2.5 inches (male) or minus 2.5 inches (female).