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NC Division of Medical Assistance
Outpatient Pharmacy
Prior Approval Criteria
Growth Hormones

Medicaid and Health Choice
Effective Date: March 4, 2002
Revised Date: February 26, 2019

Therapeutic Class Code: P1A, P7A
Therapeutic Class Description: Growth Hormones

Medication	Generic Code Number(s)	National Drug Code(s)
Genotropin	10554, 63408	
Genotropin Miniquick products	21450, 21451, 21452, 21453, 21454, 50207, 50217, 50177, 50187, 50197	
Humatrope	00575, 25957, 25963, 25969	
Norditropin ; Norditropin 15mg/1.5ml, Norditropin Nordiflex	24145, 24146, 24147, 25816, 92386	
Nutropin AQ Nuspin Injector 5mg, 10mg and 20mg	39695, 39698, 27846	
Omnitrope, Omnitrope 5mg/1.5ml CRTG, Omnitrope 10mg/1.5ml CRTG	93215, 92366, 92386	
Saizen	23695	44087100502, 54569493000 44087108801,
Tev-Tropin		57844071319
Zomacton 5mg vial; Zomacton 10mg vial	25955, 25967	
Zorbtive		44087338807
Increlex	25465	

Use of Serostim for AIDS wasting syndrome is exempted from this policy and does not require prior approval.

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Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified. **EPSDT does not apply to NCHC beneficiaries**.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.
Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.
EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

a. that is unsafe, ineffective, or experimental/investigational.
b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements
EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. Additional information on EPSDT guidelines may be accessed at http://www.ncdhhs.gov/dma/epsdt/.

Criteria (excludes Zorbtive and Increlex)

A. Adults with growth hormone deficiency

Coverage is provided in the presence of all the following:

1. Biochemical diagnosis of somatotropin deficiency by means of a negative response to a standard growth hormone (GH) stimulation test
2. This deficiency, either alone or with multiple hormone deficiencies, is a result of pituitary disease, hypothalamic disease, surgery, radiation therapy, or trauma
3. Adult beneficiaries who were diagnosed with GH deficiency in childhood must have a low level of insulin-like growth factor–1 (IGF-1) after having been off GH therapy for at least 1 month

Continuation of Therapy in adults

Adult beneficiaries with genetic causes of GH deficiency/hypopituitarism and multiple pituitary hormone deficiencies are exempt from criteria requirements.

B. Children with growth hormone deficiency

Coverage is provided in the presence of all the following:

1. GH dysfunction or lack of adequate endogenous GH documented by any of two provocative tests of less than 10mg/ml
2. Beneficiary's height must be below the third percentile for their age and gender related height
3. Epiphysis confirmed as open in beneficiaries greater than 9 years of age

C. Beneficiaries with the following conditions (no requirement for growth hormone stimulation testing):

1. Children with craniopharyngiomas
2. Children with multiple pituitary hormone deficiencies (panhypopituitarism) who have abnormal height velocity (height velocity <25th percentile for bone age) and low serum levels of IGF-1 and insulin-like growth factor binding protein–3 (IGFBP-3)
3. Children with abnormal height velocity (height velocity <25th percentile for bone age), low IGF-1/IGFBP-3 levels, and anatomic (MRI) evidence of hypopituitarism (ectopic posterior pituitary bright spot, small or hypoplastic pituitary gland or stalk, or empty sella)

4. Adequately nourished infants or children who have hypoglycemia and low GH response to hypoglycemia and who show other signs of hypopituitarism
5. Children who have received cranial irradiation with a decreased height velocity (height
   velocity <25th percentile for bone age) who show other evidence of hypopituitarism (one or more additional pituitary hormone deficiencies)

D. Coverage for a trial of GH therapy is provided for children with otherwise unexplained short stature who may pass GH stimulation tests, but who meet all of the following criteria

1. Height >2.25 standard deviations below mean for age
2. Height velocity <25th percentile for bone age
3. Bone age >2 standard deviations below mean for age
4. Low serum IGF-1/IGFBP-3

E. Coverage is provided in the absence of documented growth hormone deficiency, stimulation tests, or IGF-1 levels in the following situations

1. Beneficiaries with Turner's syndrome
2. Children with height less than 3rd percentile for chronologic age with chronic renal insufficiency
3. Beneficiaries with Prader-Willi syndrome
4. Children who were born small for gestational age (SGA) or with intrauterine growth retardation (IUGR) in whom the birth weight and/or length were more than 2 standard deviations below the mean for gestational age, and who fail to show catch-up growth by age 2 (defined as a height velocity below 1 standard deviation score, adjusted for age)

Increlex

Therapy with Increlex (IGF-I) must be reserved for children with growth failure that will not respond to GH therapy: those with GH resistance caused by a mutation in the GH receptor or post-GH receptor signaling pathway, or IGF-I gene defects, or individuals with GH gene deletions who have developed neutralizing antibodies to GH. In addition, children with severe short stature may be considered for Increlex therapy if they have failed a trial of GH therapy. Children must have a height less than 3 SDs below the mean, an IGF-I level less than 3 SDs below the mean, and normal or elevated GH levels.

Zorbtive

Therapy with Zorbtive must be reserved for beneficiaries with short bowel syndrome.

Continuation of Therapy in Children:

Coverage is provided in the presence of all of the following criteria:

1. A growth response of greater than 4.5 cm/year (pre-pubertal growth phase) or greater
   than 2.5 cm/year (post-pubertal growth phase) must occur for continuation of coverage.
2. Minimum yearly IGF-I and/or IGFBP-3 monitoring must be performed, and results must be within age-appropriate ranges.

(Children with genetic causes of GH deficiency/hypopituitarism and multiple pituitary hormone deficiencies are exempt from criteria requirements.)

Procedures:

1. The P&T recommends that a pharmacist handle all prior authorization requests for this therapeutic class.
2. The request must come from the physician's office.
3. Approval length up to one year.

References

1. Wilson TA et al. Update of guidelines for the use of growth hormone in children. *Journal of Pediatrics.* 2003. 143; 415-21
2. Maison P, Griffin S, Nicoue-Beglah M, Haddad N, Balkau B, Chanson P. Impact of growth hormone (GH) treatment of cardiovascular risk factors in GH-deficient adults: a meta-analysis of blinded, placebo controlled trials. *The Journal of Clinical Endocrinology and Metabolism.* 2004. 89(5): 2192-2199
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4. Zhou Y, Xiao-Ting W, Yang G, Zhunag W, Wei M. Clinical evidence of growth hormone, glutamine and a modified diet for short bowel syndrome: meta-analysis of clinical trials. *Asia Pac J Clin Nutr.* 2005. 14(1):98-102.
5. Davies PSW. Growth hormone therapy in Prader-Willi Syndrome. *International J of Obesity.* 2001. 25:2-7.
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7. Serono Laboratories, Inc. Serostim package insert. Randolph, MA: 2001 Jun.
8. Serono Laboratories, Inc. Saizen package insert. Randolph, MA: 2000 Sep.
9. Genentech, Inc. Protropin package insert. San Francisco, CA: 1999 Jan.
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11. Eli Lilly and Company. Humatrope package insert. Indianapolis, IN: 2001 Feb.
12. Pharmacia & Upjohn Company. Genotropin package insert. Kalamazoo, MI: 2001 Jul.
13. Ferring Pharmaceuticals, Inc. Zomacton package insert. Parsippany, NJ: 2015 Mar.

Criteria Change Log

03/04/2002	Criteria effective date
05/04/2009	Added coverage for children with craniopharyngiomas, panhypopituitarism, and unexplained short stature. Added continuation criteria
06/15/2012	Combined NC Medicaid and NC Health Choice criteria into one (no changes to criteria)
11/01/2014	Added new GCN for Nutropin
11/01/2015	Added criteria for Zomacton
02/26/2019	Removed old GCN's for Nutropin. Update name to Nutropin Nuspin