DIVISION OF HEALTH CARE FINANCING AND POLICY
NEVADA MEDICAID
DRUG USE REVIEW (DUR) BOARD
PROPOSED PRIOR AUTHORIZATION CRITERIA

Growth hormones are a covered benefit of Nevada Medicaid for recipients who meet the criteria for coverage.

1. Coverage and Limitations:
Initial authorization will be given if the following criteria are met and documented:

Requests for Genotropin® (somatropin), Humatrope® (somatropin), Norditropin® (somatropin), Nutropin® (somatropin), Omnitrope® (somatropin), Saizen® (somatropin), Tev-Tropin® (somatropin)

- Children (open epiphyses, remaining growth potential)
  1. Must have the following:
     a. The recipient has had an evaluation by a pediatric endocrinologist or pediatric nephrologist with a recommendation for growth hormone therapy.
     AND
     b. The recipient has had an evaluation ruling out all other causes for short stature.
     AND
     c. The recipient is receiving adequate replacement therapy for any other pituitary hormone deficiencies, such as thyroid, glucocorticoids or gonadotropic hormones.
     AND ONE of the following:

     d. The recipient has a diagnosis of Noonan Syndrome, Prader-Willi Syndrome or Turner Syndrome.
     AND
     The recipient's height is at least two standard deviations below the mean or below the third percentile for the patient's age and gender.

     e. The recipient has a diagnosis of chronic renal insufficiency (<75 mL/minute).
     AND
     The recipient's height is at least two standard deviations below the mean or below the third percentile for the patient's age and gender.

     f. The recipient has a diagnosis of being small for gestational age.
     AND
     The recipient is two years of age or older.
     AND
     The recipient's height is at least two standard deviations below the mean or below the third percentile for the patient's age and gender.

     g. The recipient is a newborn infant with evidence of hypoglycemia.
     AND
     The recipient has a low growth hormone level (<20 ng/mL), low for age insulin like growth factor (IGF)-1 or IGF binding protein (BP)3 (no stimulation test required for infants).

h. The recipient has a diagnosis of growth hormone deficiency or hypothalamic pituitary disease (e.g., hypopituitarism due to structure lesions/trauma to the pituitary including pituitary tumor, pituitary surgical damage, trauma, or cranial irradiation)
AND
The recipient's height is at least two standard deviations below the mean or below the third percentile for the patient's age and gender.
AND
The recipient has failed two growth hormone stimulation tests (<10 ng/mL).
OR
The recipient has failed one growth hormone stimulation tests (<10 ng/mL) and one IGF-1 or IGFBP-3 test.
OR
The recipient has failed one growth hormone stimulation tests (<10 ng/mL) or IGF-1 or IGFBP-3 test and they have deficiencies in three or more pituitary axes (e.g., thyroid stimulating hormone [TSH], luteinizing hormone [LH], follicle stimulating hormone [FSH], adrenocorticotropic hormone [ACTH] or antidiuretic hormone [ADH]).

- Adults (closed epiphyses, no remaining growth potential)
  1. Must have the following:
     a. The recipient is being evaluated by an endocrinologist.
     AND
     The recipient is receiving adequate replacement therapy for any other pituitary hormone deficiencies, such as thyroid, glucocorticoids or gonadotropic hormones.
     AND
     The recipient has a diagnosis of growth hormone deficiency or hypothalamic pituitary disease (e.g., hypopituitarism due to structure lesions/trauma to the pituitary including pituitary tumor, pituitary surgical damage, trauma, or cranial irradiation).
     AND
     The recipient has failed two growth hormone stimulation tests (<5 ng/mL).
     OR
     The recipient has failed one growth hormone stimulation tests (<5 ng/mL) and one IGF-1 or IGFBP-3 test.
     OR
     The recipient has failed one growth hormone stimulation tests (<5 ng/mL) or IGF-1 or IGFBP-3 test and has deficiencies in three or more pituitary axes (i.e. TSH, LH, FSH, ACTH, ADH).
     AND
     The recipient has severe clinical manifestations of growth hormone deficiency as evident by alterations in body composition (e.g., decreased lean body mass, increased body fat), cardiovascular function (e.g., reduced cardiac output, lipid abnormalities) or bone mineral density.

Continued authorization will be given if the following criteria are met and documented:

- Children (open epiphyses, remaining growth potential)
  1. Must have ALL of the following:
     a. The recipient has a diagnosis of chronic renal insufficiency, growth hormone deficiency, hypothalamic pituitary disease, newborn infant with evidence of hypoglycemia, Noonan Syndrome, Prader-Willi Syndrome, small for gestational age or Turner Syndrome.
     AND
     The recipient's epiphyses are open.
     AND
     The recipient's growth rate on treatment is at least 2.5 cm/year.
     AND
     The recipient does not have evidence of expanding lesion or tumor formation.
     AND
     The recipient has not undergone a renal transplant.

- Adults (closed epiphyses, no remaining growth potential)
  1. Must have the following:
     a. The recipient has a diagnosis of growth hormone deficiency or hypothalamic pituitary disease.
     AND
     There is documentation of improvement in clinical manifestation associated with growth hormone deficiency.

Requests for Serostim® (somatropin)
1. Must have ALL of the following:
   a. The recipient has a diagnosis of Human Immune Deficiency Virus (HIV) with wasting or cachexia.
   AND
   The requested medication is indicated to increase lean body mass, body weight and physical endurance.
   AND
   The recipient is receiving and is compliant with antiretroviral therapy.
   AND
   The recipient has experienced an involuntary weight loss of >10% pre-illness baseline or they have a body mass index of <20 kg/m^2.
   AND
   The recipient has experienced an adverse event, allergy or inadequate response to megestrol acetate, or the recipient has a contraindication to treatment with this agent.
   AND
   The recipient has experienced an adverse event, allergy or inadequate response to an anabolic steroid (e.g., testosterone, oxandrolone, nandrolone), or the recipient has a contraindication to treatment with these agents.

Requests for Zorbtive® (somatropin)

1. Must have ALL of the following:
    a. The recipient has a diagnosis of short bowel syndrome.
    AND
    The recipient is 18 years of age or older.
    AND
    The requested medication is being prescribed by or following consultation with a gastroenterologist.
    AND
    The recipient is receiving specialized nutritional support (e.g., high carbohydrate, low-fat diets via enteral or parenteral nutrition).

2. PA Guidelines:
Prior Authorization approval will be 12 weeks for all Serostim® (somatropin) requests.
Prior Authorization approval will be 6 months for initial requests (all other somatropin products).
Prior Authorization approval will be 1 year for requests for continuing treatment (all other somatropin products).

3. Quantity Limitations:
N/A