blue of california

GENOTROPIN (somatropin), HUMATROPE (somatropin), NORDITROPIN (somatropin), OMNITROPE (somatropin), SAIZEN (somatropin), TEV-TROPIN (somatropin), ZOMACTON (somatropin)

Diagnoses Considered for Coverage:

In Adults:

- Growth Hormone Deficiency (GHD)

In Pediatrics:

- Growth Hormone Deficiency (GHD)
- Turner's Syndrome
- Growth failure due to chronic renal insufficiency (CRF) up until renal transplant
- Prader-Willi Syndrome, and Noonan's Syndrome
- Small for Gestational Age (SGA)

Criteria Coverage:

1. **ADULTS: Growth hormone deficiency (GHD) WITH known pituitary disease:**

Initial Authorization
• Drug will be given at home by patient or the patient's caregiver, **and** • Prescribed by an endocrinologist, **and** • Evidence of pituitary disease *(defined as cranial irradiation, MRI/CT identified lesions of pituitary area, pituitary surgery or adenoma, MRI/CT confirmation of absence/abnormality of the pituitary gland or genetic defect),* **and** • Patient has failed one adult provocative growth hormone stimulation test performed after age 18 years, **and** • Intolerance or contraindication to either Nutropin or Nutropin AQ that is not expected with the requested drug, **and** • Dose does not exceed FDA maximum. ***Coverage duration:*** 1 year
Reauthorization
• Drug will be given at home by patient or the patient's caregiver, **and** • Patient is responding to growth hormone therapy, **and** • Dose does not exceed FDA approved dosing for diagnosis. ***Coverage duration:*** 1 year

2. **ADULTS: Growth hormone deficiency (GHD) WITHOUT known pituitary disease:**

Initial Authorization
• Drug will be given at home by patient or the patient's caregiver, **and**

- Prescribed by an endocrinologist, **and**
- Dose does not exceed FDA maximum, **and**
- Intolerance or contraindication to either Nutropin or Nutropin AQ that is not expected with the requested drug, **and**
- One of the following:
  - For patient with **1 or 2** documented pituitary hormone deficiencies [ACTH, PRL, LH, FSH, or TSH]:
    - Currently has low IGF-I (defined as being below the mean or 50th percentile of the reference range for sex and age) , AND has failed 1 growth hormone stimulation test within the past year, **or**
  - For patient with **3 or more** documented pituitary hormone deficiencies [ACTH, PRL, LH, FSH, or TSH]:
    - Currently has low IGF-1 (defined as being outside of or below the 2.5th percentile of the reference range for sex and age).

Coverage duration: length of benefit

3. ADULTS: Growth hormone deficiency (GHD), continuing from childhood WITH known pituitary disease:

Initial Authorization
• Drug will be given at home by patient or the patient's caregiver, **and** • Prescribed by an endocrinologist, **and** • Documented diagnosis of childhood GHD continuing into adulthood, **and** • Intolerance or contraindication to either Nutropin or Nutropin AQ that is not expected with the requested drug, **and** • Dose does not exceed FDA maximum. ***Coverage duration:*** 1 year
Reauthorization
• Drug will be given at home by patient or the patient's caregiver, **and** • Patient is responding to growth hormone therapy, **and** • Dose does not exceed FDA maximum. ***Coverage duration:*** 1year

4. ADULTS: Growth hormone deficiency (GHD), continuing from childhood WITHOUT known pituitary disease:

Initial Authorization
• Drug will be given at home by patient or the patient's caregiver, **and** • Prescribed by an endocrinologist, **and** • Documented diagnosis of childhood GHD continuing into adulthood, **and** • Patient has failed an adult provocative growth hormone stimulation test performed after 18 years of age, **and** • Intolerance or contraindication to either Nutropin or Nutropin AQ that is not expected with the requested drug, **and** • Dose does not exceed FDA maximum. ***Coverage duration:*** 1 year

Reauthorization
• Drug will be given at home by patient or the patient's caregiver, **and** • Patient is responding to growth hormone therapy, **and** • Dose does not exceed FDA maximum. ***Coverage duration:*** 1year

5. PEDIATRICS: For growth hormone deficiency (GHD) WITH known pituitary disease:

Initial Authorization
• Drug will be given at home by patient or the patient's caregiver, **and** • Prescribed by a pediatric endocrinologist, **and** • Patient has defined central nervous system (CNS) disease (e.g. CNS lesion), history of irradiation, multiple pituitary hormonal deficiencies, or genetic defect affecting the growth hormone axis, **and** • Intolerance or contraindication to either Nutropin or Nutropin AQ that is not expected with the requested drug, **and** • Patient has slowing in growth velocity, **and** • Patient failed 1 standard growth hormone provocative test (defined as a peak growth hormone level < 10ng/ml) done within 1 year prior to starting growth hormone therapy, **and** • Dose does not exceed FDA maximum. ***Coverage duration:*** 1year
Reauthorization
• Drug will be given at home by patient or the patient's caregiver, **and** • Patient is responding to growth hormone therapy, **and** • Dose does not exceed FDA maximum, **and** ***Coverage duration:*** 1year

6. PEDIATRICS: For growth hormone deficiency (GHD) WITHOUT known pituitary disease:

Initial Authorization

• Drug will be given at home by patient or the patient's caregiver, **and**
• Prescribed by a pediatric endocrinologist, **and**
• Patient's height must be 2 or more standard deviations below the mean (less than the 3rd percentile) for age and sex prior to growth hormone therapy, **and**
• Height Velocity is less than 10th percentile of normal for age and sex, tracked over at least one year prior to growth hormone therapy (see chart below), **and**
• Intolerance or contraindication to either Nutropin or Nutropin AQ that is not expected with the requested drug, **and**
• Dose does not exceed FDA maximum, **and**
• One of the following:
  • Failure of at least 2 standard growth hormone provocative tests (defined as a peak growth hormone level < 10ng/ml) done within 1 year prior to initiating GH therapy, with peak value assessed using more than one point in time (e.g. 0, 30, 60, 90, 120 minutes), **or**
  • One low insulin-like growth factor (IGF-1) test AND failure of one standard GH provocative test.

Coverage duration: 1year

Reauthorization

- Drug will be given at home by patient or the patient's caregiver, **and**
- Patient has a growth velocity of at least 3 cm/year while on growth hormone, **and**
- Dose does not exceed FDA maximum, **and**

Coverage duration: 1year

7. PEDIATRICS: For Turner's, CRF, Prader-Willi, or Noonan's Syndrome:

Initial Authorization

- Drug will be given at home by patient or the patient's caregiver, **and**
- Prescribed by a pediatric endocrinologist *(does not apply if diagnosis is CRF)*, **and**
- *For chronic renal insufficiency only*: GFR < 50 ml/min, **and**
- Intolerance or contraindication to either Nutropin or Nutropin AQ that is not expected with the requested drug, **and**
- Dose does not exceed FDA maximum.

Coverage duration: 1year

Reauthorization

- Drug will be given at home by patient or the patient's caregiver, **and**
- Dose does not exceed FDA maximum, **and**
- One of the following:
  - Patient has Turner's Prader-Willi, or Noonan's Syndrome, has no side effects to growth hormone, and is compliant with drug therapy, **or**
  - Patient has CRF and did not receive a kidney transplant within the past year

Coverage duration: 1year

8. PEDIATRICS: For Small for Gestational Age (SGA):

Initial Authorization

- Drug will be given at home by patient or the patient's caregiver, **and**
- Prescribed by a pediatric endocrinologist, **and**
- Patient's length at birth or birth weight must be 2 or more standard deviations below the mean (less than the 3rd percentile) for gestational age (adjusted for prematurity), **and**
- Patient's height is 2 or more standard deviations below the mean (less than the 3rd percentile) at 2 years of age (boys 80-81cm; girls 79-80cm), **and**
- Intolerance or contraindication to either Nutropin or Nutropin AQ that is not expected with the requested drug, **and**
- Dose does not exceed FDA maximum.

Coverage duration: 1year

Reauthorization

- Drug will be given at home by patient or the patient's caregiver, **and**

- Patient has a growth velocity of ≥ 3 cm/year while on growth hormone, **and**
- Dose does not exceed FDA maximum.

Coverage duration: 1year

Coverage Duration: see above

Effective: 4/01/2016