Updated: 07/2017
PARP Approved: 08/2017

Gateway Health
Prior Authorization Criteria
Norditropin Flexpro (somatropin)

All requests for Norditropin Flexpro (somatropin) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Norditropin Flexpro (somatropin) Prior Authorization Criteria:

The following criteria applies for all indications:

- The medication is prescribed by a specialist such as an endocrinologist or neonatologist; **AND**
- There are no contraindications to receiving recombinant growth hormone; **AND**
- Up to date chart documentation that includes an assessment is provided with each authorization request; **AND**
- The requested dose and frequency is within FDA-approved dosing recommendations

The following indication-specific criteria must also be satisfied for coverage to be provided:

- Coverage is provided for **pediatric growth hormone deficiency** when the following criteria is met:
    - Member's height must be below the third percentile for their age and gender related height OR > 2 standard deviations below the mid-parental height percentile for gender and age;
      AND
    - Diagnosis confirmed by 2 provocative stimulation tests producing peak growth hormone concentrations < 10ng/ml
      OR
    - Patient has a significant structural abnormality affecting the pituitary and 1 provocative stimulation test producing peak growth hormone concentrations < 10ng/ml
        - Note: Only one stimulation test is needed in the presence of a pituitary abnormality

      OR
    - Patient has panhypopituitarism (defined as at least 3 pituitary hormone deficiencies)
        - Note: No stimulation tests are needed in the setting of panhypopituitarism

      OR
    - Insulin growth factor-1 (IGF-1) a.k.a. somatomedin C, or IGF binding protein-3 (IGFBP-3) levels below normal range
      OR
    - Radiographic documentation that bone age is > 2 standard deviations below the mean for chronological age
      OR

- Patient produces two normal stimulation tests but has a height ≥ 2.25 standard deviations below the age related mean and a growth velocity below the 25th percentile for bone age
    - Note: When growth deficiency is significant (meeting the definition stated) results of stimulation tests may not be as clinically significant

AND

- Epiphyses confirmed as open in female patients ≥ 12 years of age and in male patients ≥ 14 years of age and in patients in Tanner stage 3 or higher through X-ray of the wrist

AND

- The member's growth failure is not due to idiopathic short stature, familial short stature or constitutional growth delay.

- Coverage is provided for growth failure in children born **small for gestational age (SGA)**, (defined as a height ≥ 2 standard deviations below the mean for age and gender, and a birth weight < 2500 g at a gestational age ≥ 37 weeks, or weight or length at birth > 2 standard deviations below the mean for gestational age) who fail to manifest catch up growth by age 2.
    - Note: Failure to reach catch up growth is defined as a height ≥ 2 standard deviations below the age/gender related mean

- Coverage is provided for a diagnosis of pediatric growth failure, (defined as a height ≥ 2 standard deviations below the age and gender related mean) due to **Turner's syndrome** when the following criteria is met:
    - Member is female; **AND**
    - Diagnosis was confirmed by karyotyping; **AND**
    - Epiphyses are open

- Coverage is provided for a diagnosis of pediatric growth failure (defined as a height ≥ 2 standard deviations below the age and gender related mean) due to **Noonan's Syndrome** when the following criteria is met:
    - Member has clinical features consistent with the typical presentation of this condition OR diagnosis has been confirmed by genetic testing; **AND**
    - Epiphyses are open

- Coverage is provided for **adult growth hormone deficiency**, defined as recipients age 18 and older or any age with closed epiphyses and who have a growth hormone stimulation test with peak growth hormone concentrations < 5ng/ml as a result of:
    - Childhood onset growth hormone deficiency
    - Pituitary or hypothalamic disease
    - Surgery or radiation therapy
    - Trauma
    - A GH stimulation test is not needed when the patient has panhypopituitarism (≥ 3 pituitary hormone deficiencies) or a structural abnormality affecting the pituitary and an IGF-1 level below the reference range as indicated on the assay.

- An adult transitioning from pediatric growth hormone deficiency must have been off growth hormone for at least one month

- Coverage Duration and Reauthorization Criteria:
  - Pediatric human growth hormone deficiency, growth failure in children SGA, Turner's Syndrome, Noonan's Syndrome
    - Benefit approved for 12 months and is renewable in members with open epiphyses, a growth velocity of ≥ 2 cm/yr, attestation of ongoing monitoring of IGF-1 level, and the member has not reached their expected final adult height.

  - Adult growth hormone deficiency syndrome
    - Benefit approved for 6 months and is renewable in the presence of clinical benefit (i.e., increase in total lean body mass, increase in IGF-1, or increase in exercise capacity) and attestation of ongoing monitoring of IGF-1 level.

- Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

- When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must over ride criteria when, in their professional judgment, the requested medication is medically necessary.

References:

1) Norditropin [package insert]. Plainsboro, NJ: Novo Nordisk; April 2017.
2) Wilson TA, *et al*. Update of Guidelines for the Use of Growth Hormone in Children: The Lawson Wilkens Pediatric Endocrinology Society Drug and Therapeutics Committee; *J Peds*. October 2003: 415-421
3) Hardin DS. Treatment of Short Stature and Growth Hormone Deficiency in Children with Somatotropin (rDNA origin). *Biologics: Targets & Therapy*. 2008:2(4); 655-661
4) American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for Growth Hormone Use in Growth Hormone-Deficient Adults and Transition Patients – 2009 Update. *Endocr Practice*. 2009;15 (suppl 2)
5) American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for Growth Hormone Use in Adults and Children – 2003 Update. *Endocr Practice*. 2003;9(1)
6) Molitch ME, *et al*. Evaluation and Treatment of Adult Growth Hormone Deficiency: an Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2011 Jun;96(6): 1587-1609
7) Mahesh S, Kaskel F. Growth Hormone Axis in Chronic Kidney Disease. *Pediatr Nephrol*. January 2008; 23(1):41-48
8) KDIGO Clinical Practice Guideline for the Diagnosis, Evaluation, Prevention and Treatment of Chronic Kidney Disease – Mineral and Bone Disorder (CKD-MBD). Kidney International. August 2009; 76 (113)

9) Bondy CA. Care of girls and women with Turner Syndrome: A Guideline of the Turner Syndrome Study Group. *J Clin Endocrinol Metab*. 2007;92(1):10-25.
10) Snyder PJ. Growth hormone deficiency in adults. UpToDate. Updated June 2017. Accessed July 2017.