AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Ngenla	Page:	1 of 4
Effective Date:	6/9/2025	Last Review Date:	5/27/2025
Applies to:	☒New Jersey ☒Maryland		

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Ngenla under the patient's prescription drug benefit.

Description:

Ngenla is indicated for the treatment of pediatric patients aged 3 years and older who have growth failure due to an inadequate secretion of endogenous growth hormone.

Applicable Drug List:

Ngenla

Policy/Guideline:

FORMULARY PREFERENCING
The patient is unable to take Norditropin, the preferred formulary alternative for the given diagnosis, due to a trial and inadequate treatment response or intolerance, or a contraindication.

Documentation:

Submission of the following information is necessary to initiate the prior authorization review for both initial and continuation of therapy requests (where applicable):

A. Medical records supporting the diagnosis of neonatal growth hormone (GH) deficiency
B. Pretreatment growth hormone provocative test result(s) (laboratory report or medical record documentation)
C. Growth chart
D. Pretreatment IGF-1 level (laboratory report or medical record documentation)*
E. The following information must be provided for all continuation of therapy requests:
    1. Total duration of treatment (approximate duration is acceptable)
    2. Date of last dose administered
    3. Approving health plan/pharmacy benefit manager
    4. Date of prior authorization/approval
    5. Prior authorization approval letter

* IGF-1 levels vary based on the laboratory performing the analysis. Laboratory-specific values must be provided to determine whether the value is within the normal range.

Criteria for Initial Approval:

Pediatric growth hormone (GH) deficiency
Authorization of 12 months may be granted to members with pediatric GH deficiency 3 years of age and older when EITHER criteria A. or B. below is met:

A. Member was diagnosed with GH deficiency as a neonate. Medical records must be available to support the diagnosis of neonatal GH deficiency (e.g., hypoglycemia with random GH level, evidence of multiple pituitary hormone deficiency, chart notes, or magnetic resonance imaging [MRI] results).
B. Member meets ALL of the following:
    1. Member has EITHER:
        i. Two pretreatment pharmacologic provocative GH tests with both results demonstrating a peak GH level < 10 ng/mL, OR
        ii. A documented pituitary or CNS disorder (refer to Appendix) and a pretreatment IGF-1 level > 2 standard deviations (SD) below the mean
    2. Member meets one of the following:
        i. Pretreatment height is > 2 SD below the mean and 1-year height velocity is > 1 SD below the mean, OR
        ii. Pretreatment 1-year height velocity is > 2 SD below the mean
    3. Epiphyses are open

Continuation of Therapy:

Pediatric GH deficiency

Authorization of 12 months may be granted for continuation of therapy when ALL of the following criteria are met:

A. Member is currently receiving the requested medication or another growth hormone product (e.g., Norditropin) indicated for pediatric GH deficiency
B. Epiphyses are open[1,2] (confirmed by X-ray or X-ray is not available[9])
C. Member's growth rate is > 2 cm/year[2,5] unless there is a documented clinical reason for lack of efficacy (e.g., on treatment less than 1 year, nearing final adult height/late stages of puberty)[6,9]

Appendix:

Examples of Hypothalamic/Pituitary/CNS Disorders

1. Congenital genetic abnormalities
    a. Transcription factor defects (PIT-1, PROP-1, LHX3/4, HESX-1, PITX-2)
    b. Growth hormone releasing hormone (GHRH) receptor gene defects
    c. GH secretagogue receptor gene defects
    d. GH gene defects
2. Congenital structural abnormalities
    a. Optic nerve hypoplasia/septo-optic dysplasia
    b. Agenesis of corpus callosum
    c. Empty sella syndrome
    d. Ectopic posterior pituitary
    e. Pituitary aplasia/hypoplasia
    f. Pituitary stalk defect

g. Holoprosencephaly
h. Encephalocele
i. Hydrocephalus
j. Anencephaly or prosencephaly
k. Arachnoid cyst
l. Other mid-line facial defects (e.g., single central incisor, cleft lip/palate)
m. Vascular malformations

3. Acquired structural abnormalities (or causes of hypothalamic/pituitary damage)
   a. CNS tumors/neoplasms (e.g., craniopharyngioma, glioma/astrocytoma, pituitary adenoma, germinoma)
   b. Cysts (Rathke cleft cyst or arachnoid cleft cyst)
   c. Surgery
   d. Radiation
   e. Chemotherapy
   f. CNS infections
   g. CNS infarction
   h. Inflammatory processes (e.g., autoimmune hypophysitis)
   i. Infiltrative processes (e.g., sarcoidosis, histiocytosis, hemochromatosis)
   j. Head trauma/traumatic brain injury
   k. Aneurysmal subarachnoid hemorrhage
   l. Perinatal or postnatal trauma
   m. Surgery of the pituitary or hypothalamus

Approval Duration and Quantity Restrictions:

Approval:
Initial and renewal duration: 12 months

Quantity Level Limit: Reference Formulary for drug specific quantity level limits

References:

1. Ngenla [package insert]. New York, NY: Pfizer; June 2023.
2. Gharib H, Cook DM, Saenger PH, et al. American Association of Clinical Endocrinologists Growth Hormone Task Force. Medical guidelines for clinical practice for growth hormone use in adults and children 2003 Update. Endocr Pract. 2003;9(1):64-76.
3. National Institute for Clinical Excellence: Guidance on the use of human growth hormone (somatropin) for the treatment of growth failure in children. May 2010. http://www.nice.org.uk/guidance/ta188. Accessed January 20, 2025.
4. Wilson TA, Rose SR, Cohen P, et al. Update of Guidelines for the Use of Growth Hormone in Children: The Lawson Wilkins Pediatric Endocrinology Society Drug and Therapeutics Committee. J Pediatr. 2003;143:415-421.
5. Franklin SL, Geffner ME. Growth hormone: the expansion of available products and indications. Pediatr Clin North Am. 2011;58:1141-1165.

6. Grimberg A, DiVall SA, Polychronakos C, et al. Guidelines for growth hormone and insulin-like growth factor-I treatment in children and adolescents: growth hormone deficiency, idiopathic short stature, and primary insulin-like growth factor-I deficiency. Horm Res Paediatr. 2016;86:361-397.