Commercial PA Criteria

Effective: October 13, 2023

Prior Authorization: Ngenla (somatrogon-ghla)

Products Affected: Ngenla (somatrogon-ghla), subcutaneous injection

Medication Description: Ngenla, a long-acting human growth hormone analog, is indicated for the treatment of growth failure due to inadequate secretion of growth hormone in pediatric patients ≥ 3 years of age.

Ngenla is a human growth hormone analog which is comprised of the amino acid sequence of human growth hormone with an added three copies of the C-terminal peptide of human chorionic gonadotropin. The addition of the C-terminal peptides extends the half-life. Ngenla binds to the growth hormone receptor which initiates changes in growth and metabolism and has also been shown to increase insulin-like growth factor-1 (IGF-1) serum concentrations.

Covered Uses:

1. Treatment of pediatric patients aged 3 years and older who have growth failure due to an inadequate secretion of endogenous growth hormone.

Exclusion Criteria:

1. Acute critical illness after open heart surgery, abdominal surgery or multiple accidental trauma
2. Acute respiratory failure
3. Hypersensitivity to somatrogon-ghla or any of the excipients
4. Closed epiphyses
5. Active malignancy due to the risk of malignancy progression
6. Active proliferative or severe non-proliferative diabetic retinopathy
7. Prader-Willi syndrome in those who are severely obese, have a history of upper airway obstruction or sleep apnea, or have severe respiratory impairment, due to the risk of sudden death

Required Medical Information:

1. Diagnosis
2. Medical History

Prescriber Restriction: Medication must be prescribed by, or in consultation with, an endocrinologist or pediatric endocrinologist

Age Restriction: Patient must be 3 years and older

Coverage Duration: 12 months

Other Criteria:

ConnectiCare

Initial Approval Criteria

1. **Growth Hormone Deficiency in a Pediatric Patient (≥ 3 years of age to < 18 years of age).** Initial Therapy with any Growth Hormone Agent. Approve if the patient meets one of the following (i, ii, iii, iv, **OR** v):
    i. Patient meets BOTH of the following criteria (a **AND** b):
        a) Patient meets at least ONE of the following criteria (1 **OR** 2):
            (1) Patient has had two growth hormone stimulation tests performed with any of the following agents: levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND both tests show an inadequate response as defined by a peak growth hormone response which is below the normal reference range as determined by the testing laboratory; **OR**
            (2) Patient meets BOTH of the following criteria (i **AND** ii):
                (a) Patient has had at least one growth hormone stimulation test performed with any of the following agents: levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND the test shows an inadequate response as defined by a peak growth hormone response which is below the normal reference range as determined by the testing laboratory; **AND**
                (b) Patient has at least one risk factor for growth hormone deficiency *(for example, the height for age curve has deviated downward across two major height percentiles [e.g., from above the 25th percentile to below the 10th percentile]; the child's growth rate is less than the expected normal growth rate based on age and gender; low insulin-like growth factor [IGF]-1 and/or IGFBP-3 levels; the child has a very low peak growth hormone level on provocative testing as defined by the prescribing physician; the child's growth velocity is less than the 10th percentile for age and gender [height velocity percentile is NOT the same as height-for-age percentile]; the patient is status post craniopharyngioma resection; the patient has optic nerve hypoplasia; the patient has a growth hormone gene deletion);* **AND**
        b) Patient has been evaluated by an endocrinologist.
    ii. Patient has undergone brain radiation or tumor resection AND meets BOTH of the following criteria (a **AND** b):
        a) Patient meets at least ONE of the following criteria (1 **OR** 2):
            (1) Patient meets BOTH of the following criteria (i **AND** ii):
                (i) Patient has had one growth hormone stimulation test with any of the following agents: levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon; **AND**
                (ii) The test shows an inadequate response as defined by a peak growth hormone response which is below the normal reference range as determined by the testing laboratory; **OR**
            (2) Patient has a deficiency in at least one other pituitary hormone (i.e., adrenocorticotropic hormone, thyroid-stimulating hormone, gonadotropin [luteinizing hormone and/or follicle stimulating hormone deficiency are counted as one deficiency], or prolactin); **AND**
        b) Patient has been evaluated by an endocrinologist.
    iii. Patient has congenital hypopituitarism AND meets BOTH of the following (a **AND** b):
        a) Patient meets at least ONE of the following criteria (1, 2, **OR** 3):
            (1) Patient meets BOTH of the following criteria (i **AND** ii):
                (i) Patient has had one growth hormone stimulation test with any of the following agents: levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon; **AND**
                (ii) The test shows an inadequate response as defined by a peak growth hormone response which is below the normal reference range as determined by the testing laboratory; **OR**

(2) Patient has a deficiency in at least one other pituitary hormone (i.e., adrenocorticotropic hormone, thyroid-stimulating hormone, gonadotropin [luteinizing hormone and/or follicle stimulating hormone deficiency are counted as one deficiency], or prolactin); **OR**

(3) Patient has the imaging triad of ectopic posterior pituitary and pituitary hypoplasia with abnormal pituitary stalk; **AND**

b) Patient has been evaluated by an endocrinologist.

iv. Patient has multiple pituitary hormone deficiencies and meets BOTH of the following (a **AND** b):
Note: Growth hormone deficiency may occur in combination with other pituitary hormone deficiencies and is referred to as hypopituitarism, panhypopituitarism, or multiple pituitary hormone deficiency.

a) Patient meets at least ONE of the following criteria (1 **OR** 2):

(1) Patient has three or more of the following pituitary hormone deficiencies: somatropin (growth hormone), adrenocorticotropic hormone, thyroid-stimulating hormone, gonadotropin (luteinizing hormone and/or follicle stimulating hormone deficiency are counted as one deficiency), and prolactin; OR

(2) Patient meets BOTH of the following criteria (i **AND** ii):

(i) Patient has had one growth hormone stimulation test with any of the following agents: levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon; **AND**

(ii) The test shows an inadequate response as defined by a peak growth hormone response which is below the normal reference range as determined by the testing laboratory; **AND**

b) Patient has been evaluated by an endocrinologist.

v. Patient has had a hypophysectomy (surgical REMOVAL of pituitary gland).

vi. In addition to the above criteria, Ngenla will be approved if the patient has had an intolerance to, or treatment failure of, Norditropin.

Renewal Criteria

A. Patient is Currently Receiving Ngenla or is switching to Ngenla from another Growth Hormone Agent (Patient has been established on either therapy for ≥ 10 months). Approve if the patient meets one of the following (i or ii):

i. Patient is < 12 years of age: Height has increased by ≥ 2 cm/year in the most recent year; **OR**

ii. Patient is ≥ 12 years of age and < 18 years of age: Patient meets both of the following (a **AND** b):

a. Height has increased by ≥ 2 cm/year in the most recent year; **AND**

b. Patient's epiphyses are open.

References:

1. Ngenla™ subcutaneous injection [prescribing information]. New York, NY: Pfizer; June 2023
2. Ngenla. LexiComp [database online]. New York, NY: Pfizer Labs; June 2023. Accessed on October 10, 2023.
3. Ngenla. IPD Analytics. Available at: http://secure.ipdanalytics.com. Accessed on October 10, 2023
4. Ngenla. IBM Micromedex [database online] Pfizer Labs (per FDA), New York, NY. Available at: https://www.micromedexsolutions.com. Updated August 10, 2023. Accessed October 10, 2023.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date

1	New Policy	New Policy	All	10/13/2023