HAP CareSource™

PHARMACY POLICY STATEMENT
HAP CareSource™ Marketplace

DRUG NAME	Ngenla (somatrogon-ghla)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Ngenla is a human growth hormone analog indicated for treatment of pediatric patients aged 3 years and older who have growth failure due to inadequate secretion of endogenous growth hormone. It is administered once weekly subcutaneously. Growth hormone deficiency involves inadequate secretion of growth hormone from the pituitary gland.
Ngenla was noninferior when compared to daily somatropin in a phase 3 clinical trial. Ngenla demonstrated higher annualized height velocity at week 52 compared to daily somatropin. Patients in the Ngenla experienced an annualized height velocity of 10.1 cm/year versus the daily somatropin group which achieved an annualized height velocity of 9.8 cm/year.

Ngenla (somatrogon-ghla) will be considered for coverage when the following criteria are met:

Pediatric Growth Hormone Deficiency

For **initial** authorization:
1. Member is at least 3 years of age; AND
2. Medication must be prescribed by or in consultation with an endocrinologist; AND
3. Member was diagnosed with congenital hypopituitarism as a newborn and had **BOTH** of the following:
   a) Hypoglycemia with a serum GH concentration ≤ 5 µg/L;
   b) At least **one** additional pituitary hormone deficiency (see appendix C) or classical imaging triad (ectopic posterior pituitary and pituitary hypoplasia with abnormal stalk); OR
4. Member has documentation of **BOTH** of the following:
   a) Hypothalamic-pituitary defect (see appendix A);
   b) At least **one** additional pituitary hormone deficiency (see appendix C); OR
5. Member must have documentation of **TWO** pre-treatment stimulation tests with a peak serum growth hormone concentration < 10 ng/mL (must include lab results with reference ranges); AND
6. Member must have a documented 6-month trial and failure of Omnitrope 5.8 mg vial; AND
7. Member must have a pretreatment height (must include growth charts) of > 2 SD below the mean for age and gender; AND
8. Member must have a pretreatment height velocity (must include growth charts) below the 25th percentile for age and gender; AND
9. Member does **NOT** have a history of active malignancy; AND
10. Member's weight is provided for dose calculation; AND
11. If member is age 12 or older, radiographic evidence the member's epiphyses are open (x-ray results must be included).

12. **Dosage allowed/Quantity limit:** 0.66 mg/kg administered once weekly subcutaneously.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Member has a growth rate of at least 2 cm/year; AND
2. If member is age 12 or older, radiographic evidence the member's epiphyses are open (x-ray results must be included).

If all the above requirements are met, the medication will be approved for an additional 12 months.

HAP CareSource considers Ngenla (somatrogon-ghla) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
08/15/2023	New policy for Ngenla created.

References:

1. Ngenla [prescribing information]. Ringaskiddy, Cork, Ireland: Pfizer Ireland Pharmaceuticals; 2023.
2. Deal CL, Steelman J, Vlachopapadopoulou E, et al. Efficacy and Safety of Weekly Somatrogon vs Daily Somatropin in Children With Growth Hormone Deficiency: A Phase 3 Study. *J Clin Endocrinol Metab.* 2022;107(7):e2717-e2728. doi:10.1210/clinem/dgac220
3. Growth Hormone Research Society. Consensus guidelines for the diagnosis and treatment of growth hormone (GH) deficiency in childhood and adolescence: summary statement of the GH Research Society. GH Research Society. *J Clin Endocrinol Metab*. 2000;85(11):3990-3993. doi:10.1210/jcem.85.11.6984
4. Pediatric Endocrine Society (PES) Guidelines for growth Hormone and insulin-like growth factor-1 treatment in children and adolescents; *Horm Res Paediatr.* 2016;86(6):361-397
5. Cohen P, Rogol AD, Deal CL, et al. Consensus statement on the diagnosis and treatment of children with idiopathic short stature: a summary of the Growth Hormone Research Society, the Lawson Wilkins Pediatric Endocrine Society, and the European Society for Paediatric Endocrinology Workshop. *J Clin Endocrinol Metab.* 2008;93(11):4210-4217. doi:10.1210/jc.2008-0509

Effective date: 01/01/2025
Creation date: 08/15/2023

Appendix A:

A) Acquired structural abnormalities

- CNS tumor or neoplasm (craniopharyngioma, glioma, pituitary adenoma, etc.)

- Cysts (Rathke cleft cyst or arachnoid cleft cyst)
- Surgery
- Radiation
- Chemotherapy
- CNS infection
- CNS infarction (e.g., Sheehan's syndrome)
- Inflammatory lesions (e.g., autoimmune hypohysitis)
- Infiltrative lesions (e.g., sarcoidosis, histiocytosis)
- Head trauma or traumatic brain injury
- Aneurysmal subarachnoid hemorrhage
- Panhypopituitarism

B) Congenital abnormalities

- Known genetic mutations in growth-hormone releasing hormone (GHRH) receptor, GH gene, GH receptor or pituitary transcription factors
- Optic nerve hypoplasia/septo-optic dysplasia
- Empty sella syndrome
- Ectopic posterior pituitary
- Pituitary aplasia/hypoplasia
- Pituitary stalk defect
- Anencephaly or prosencephaly
- Other mid-line defects
- Vascular malformations

Appendix B:

A) Congenital and acquired abnormalities that do not require adult testing

- Genetic
- Transcription factor defects (PIT-1, PROP-1, LHX3/4, HESX-1, PITX-2)
- GHRH receptor-gene defects
- GH-gene defects
- GH-receptor/post-receptor defects
- Associated with brain structural defects
- Single central incisor
- Cleft lip/palate
- Perinatal insults

Appendix C:

A) Pituitary hormones (other than growth hormone)

- Adrenocorticotropic hormone (ACTH)
- Antidiuretic hormone (ADH)
- Follicle stimulating hormone (FSH)
- Luteinizing hormone (LH)

- Oxytocin
- Prolactin
- Thyroid stimulating hormone (TSH)