HAP CareSource™

PHARMACY POLICY STATEMENT
HAP CareSource™ Marketplace

DRUG NAME	Skytrofa (lonapegsomatropin)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Skytrofa (lonapegsomatropin) is a sustained-release growth hormone product. It is indicated for patients one year of age or older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous growth hormone. It is administered as a once-weekly subcutaneous injection.
In the pivotal head-to-head clinical trial, once weekly Skytrofa was compared to daily Genotropin. Skytrofa demonstrated higher annualized height velocity at week 52 compared to Genotropin. Patients in the Skytrofa group experienced an annualized height velocity of 11.2 cm/year versus the Genotropin group who experienced annualized height velocity growth of 10.3 cm/year.

Skytrofa (lonapegsomatropin) will be considered for coverage when the following criteria are met:

Pediatric Growth Hormone Deficiency

For **initial** authorization:

1. Member is at least 1 year of age; AND
2. Member weighs at least 11.5kg; AND
3. Medication must be prescribed by or in consultation with an endocrinologist; AND
4. 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
5. 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
6. 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
7. Member must have a documented 6-month trial and failure of Omnitrope 5.8 mg vial; AND
8. Member must have a pretreatment height (must include growth charts) of > 2 SD below the mean for age and gender; AND
9. Member must have a pretreatment height velocity (must include growth charts) below the 25th percentile for age and gender; AND
10. Member does **NOT** have a history of active malignancy; AND
11. Member's weight is provided for dose calculation; AND
12. If member is age 12 or older, radiographic evidence the member's epiphyses are open (x-ray results must be included).
13. **Dosage allowed/Quantity limit**: 0.24mg/kg given subcutaneously once weekly.

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 Skytrofa (lonapegsomatropin) 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
10/13/2021	Skytrofa policy creation
08/29/2023	Increased Omnitrope trial from 90 days to 6 months; updated requirements for diagnosis of GHD including when testing is not required; updated appendix, added/updated references; added exclusion of active malignancy; added in consultation with for prescriber specialty; added documentation of height velocity below the 25th percentile; added documentation of weight for dose calculation.

References:

1. Skytrofa [package insert]. Laval, Quebec, CA; Prometric Bioproduction, Inc.; 2022.
2. Boguszewski MC. Growth hormone deficiency and replacement in children. *Rev Endocr Metab Disord*. 2021 Mar; 22: 101–108.
3. 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
4. Rogol AD, Hayden GF. Etiologies and early diagnosis of short stature and growth failure in children and adolescents. *J Pediatr*. 2014 May;164(5 Suppl):S1-14.e6
5. National Institute for Clinical Excellence: Guidance on the use of human growth hormone (somatropin) for the treatment of growth failure in children. May 2010
6. Wilson TA, Rose SR, Cohen P, et al. Update of guidelines for the use of growth hormone in children: The Lawson Wilkins Endocrinology Society Drug and Therapeutics Committee. *J Pediatr*. 2003; 143: 415-421

Effective date: 01/01/2025
Revised date: 08/29/2023

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)