PHARMACY POLICY STATEMENT
Ohio Medicaid

DRUG NAME	Skytrofa (lonapegsomatropin)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Skytrofa (lonapegsomatropin) was approved by the FDA on August 25, 2021 is 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 one year of age or older and weighs at least 11.5kg;
2. Medication must be prescribed by an endocrinologist; AND
3. Member must have a diagnosis of GHD confirmed by **one** of the following:
   a) Two pre-treatment stimulation tests with a peak serum growth hormone concentration < 10 ng/mL (must include lab results with reference ranges); OR
   b) One pre-treatment treatment stimulation test with a peak serum growth hormone concentration < 10 ng/mL (must include lab results with reference ranges) AND one of the following:
      i) Documentation of structural abnormalities of the growth hormone axis (see appendix)
      ii) Documentation of congenital abnormalities of the growth hormone axis (see appendix)
      iii) Documentation of at least two other pituitary growth hormone deficiencies (see appendix)
4. Member must have a pretreatment height (must include growth charts) of > 2 SD below the mean for age and gender; AND
5. Member must have a documented 90-day trial and failure of Omnitrope 5.8 mg vial; AND
6. If member is age 12 or older, radiographic evidence the member's epiphyses are open (x-ray results must be included).
7. **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**:
Skytrofa will be reauthorized when chart notes show at least one of the following:
1. Member has a growth rate of at least 2 cm/year;
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.

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

References:

1. Skytrofa [package insert]. Laval, Quebec, CA; Prometric Bioproduction, Inc.; June 2021.
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: 04/01/2022
Creation date: 10/13/2021

Appendix:

1) 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 or multiple pituitary hormone deficiency

2) 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
    - Vascular malformations

3) Pituitary hormones, other than growth hormone (GH)
    - Adrenocorticotropic hormone (ACTH)
    - Antidiuretic hormone (ADH)
    - Follicle stimulating hormone (FSH)
    - Luteinizing hormone (LH)
    - Oxytocin
    - Prolactin
    - Thyroid stimulating hormone (TSH)