Louisiana Medicaid
Lonapegsomatropin-tcgd (Skytrofa™)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for lonapegsomatropin-tcgd (Skytrofa™).

Additional Point-of-Sale edits may apply.

*This agent may have a **Black Box Warning** and/or are subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety Regulations. Please refer to individual prescribing information for details.*

ADULTS AND CHILDREN		
Somatropin Brand Example	**Required ICD-10 Codes**	**Diagnosis Description**
Skytrofa™	**E23.0** **E23.1** **E89.3**	Growth Hormone Deficiency (GHD) - Adult, Children o Iatrogenic Hypopituitarism o Drug-induced Hypopituitarism o Post Procedural Hypopituitarism

Approval Criteria

- The recipient has an appropriate diagnosis (see table above); **AND**
- The growth hormone is prescribed by, or the request states that the medication is prescribed in consultation with, an endocrinologist; **AND**
- Previous use of a preferred product – **ONE** of the following is required:
    - The recipient has had a *treatment failure* with an adequate trial (3 months) of at least one preferred product that is indicated for the treatment of growth hormone deficiency (see Growth Deficiency – Growth Hormones on PDL); **OR**
    - The recipient has had an *intolerable side effect* with at least one preferred product that is indicated for the treatment of growth hormone deficiency (see Growth Deficiency – Growth Hormones on PDL); **OR**
    - The recipient has *documented contraindication(s)* to all of the preferred products that are indicated for the treatment of growth hormone deficiency (see Growth Deficiency – Growth Hormones on PDL); **OR**
    - There is *no preferred product appropriate* to use for the condition being treated (see Growth Deficiency – Growth Hormones on PDL);
      AND
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing

information have been completed as of the date of the request and will be repeated as recommended; **AND**

- The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling; **AND**
- There is confirmation of open growth plates in recipients older than 12 years of age (if applicable).

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of initial and reauthorization approval: 12 months

Reference

Skytrofa (lonapegsomatropin-tcgd) [package insert]. Palo Alto, CA: Ascendis Pharma, Inc; August 2021. https://ascendispharma.us/products/pi/skytrofa/skytrofa_pi.pdf

Revision / Date	**Implementation Date**
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