STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LONAPEGSOMATROPIN-TCGD

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LONAPEGSOMATROPIN-TCGD	SKYTROFA	47565		GPI-10 (3010000380)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication being used for **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature (ISS)

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.
   If no, continue to #2.

2. Does the patient have a diagnosis of growth failure due to inadequate secretion of endogenous growth hormone and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older AND weighs at least 11.5kg
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - The patient meets at least **ONE** of following criteria for short stature:
     - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
     - Height velocity less than the 25th percentile for age
     - Documented low peak growth hormone (less than 10 ng/mL) on two GH stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 SD below the mean for same age and gender

   If yes, **approve for 12 months for all strengths by GPID or GPI-14 with the following quantity limits:**
   - **Skytrofa 3mg, 3.6mg, 4.3mg, 5.2mg, 6.3mg, 13.3mg: #1 cartridge per week.**
   - **Skytrofa 7.6mg, 9.1mg, 11mg: #2 cartridges per week.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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LONAPEGSOMATROPIN-TCGD

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LONAPEGSOMATROPIN-TCGD (Skytrofa)** requires the following rule(s) be met for approval:

A. You have growth failure due to an inadequate secretion of endogenous (from your own body) growth hormone
B. Skytrofa is not being used for the treatment of **ANY** of the following conditions:
   1. Athletic enhancement
   2. Anti-aging purposes
   3. Idiopathic short stature (ISS: a type of growth condition)
C. You are 1 year of age or older and weigh at least 11.5 kg
D. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
E. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
F. You meet at least ONE of the following criteria for short stature:
   1. Your height is at least 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender
   2. Your height velocity is less than the 25th percentile for your age
   3. You have documented low peak growth hormone (less than 10ng/mL) on two GH (growth hormone) stimulation tests or insulin-like growth factor 1 (IGF-1) at least 2 standard deviations below the mean for your age and gender

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Is the requested medication being used for **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature (ISS)

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   If no, continue to #2.

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LONAPEGSOMATROPIN-TCGD

RENEWAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of growth failure due to inadequate secretion of endogenous growth hormone and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand OR the patient has not completed prepubertal growth)
   - The patient meets ONE of the following:
     - Annual growth velocity of 2 cm or more compared with what was observed from the previous year
     - Annual growth velocity of 1 cm or more compared with what was observed from the previous year for patients that are near terminal phase of puberty

   If yes, **approve for 12 months for all strengths by GPID or GPI-14 with the following quantity limits:**
   - **Skytrofa 3mg, 3.6mg, 4.3mg, 5.2mg, 6.3mg, 13.3mg: #1 cartridge per week.**
   - **Skytrofa 7.6mg, 9.1mg, 11mg: #2 cartridges per week.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LONAPEGSOMATROPIN-TCGD (Skytrofa)** requires the following rule(s) be met for renewal:
   A. You have growth failure due to an inadequate secretion of endogenous (from your own body) growth hormone
   B. Skytrofa is not being used for the treatment of **ANY** of the following conditions:
      1. Athletic enhancement
      2. Anti-aging purposes
      3. Idiopathic short stature (ISS: a type of growth condition)
   C. Therapy is prescribed by or given in consultation with an endocrinologist (a type of hormone doctor)
   D. Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand or you have not completed prepubertal growth)
   E. You meet ONE of the following:
      1. Your annual growth velocity is 2 cm or more compared with what was observed from the previous year
      2. Your annual growth velocity is 1 cm or more compared with what was observed from the previous year if you are near the terminal (end) phase of puberty

   (Renewal denial text continued on next page)

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LONAPEGSOMATROPIN-TCGD

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Skytrofa.

REFERENCES

- Skytrofa [Prescribing Information]. Palo Alto, CA: Ascendis Pharma US, Inc., August 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective:11/01/21
Created: 10/21
Client Approval: 10/21
P&T Approval: 01/22