



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOMATROGON-GHLA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOMATROGON-GHLA	NGENLA	47896		GPI-10 (3010001500)	

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 (GH) and meet **ALL** of the following criteria?

- The patient is 3 to 17 years of age
- Therapy is prescribed by or in consultation with an endocrinologist
- The patient has open epiphyses (as confirmed by radiograph of the wrist and hand)

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ONE** of following criteria?

- The patient's height is at least 2 standard deviations (SD) below the mean height for normal children of the same age and gender
- The patient has a height velocity that is less than 25th percentile for age
- The patient has a low peak growth hormone (less than 10 ng/mL) on two GH stimulation tests, OR has an insulin-like growth factor 1 (IGF-1) that is at least 2 SD below the mean for same age and gender

If yes, **approve for 12 months by HICL or GPI-10.**

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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SOMATROGON-GHLA

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 **SOMATROGON-GHLA (Ngenla)** requires the following rule(s) be met for approval:

- A. You have growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone
- B. You are 3 to 17 years of age
- C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
- D. You have open epiphyses (end part of long bone) as confirmed by a radiograph (type of imaging test) of the wrist and hand
- E. You meet at ONE of the following criteria:
 - 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 low peak growth hormone levels (less than 10 ng/mL) on two GH (growth hormone) stimulation tests, OR an insulin-like growth factor 1 (IGF-1) level at least 2 standard deviations below the mean for your age and gender
- F. Request for Ngenla will NOT be approved for athletic enhancement, anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

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.

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SOMATROGON-GHLA

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.

2. Does the patient have a diagnosis of growth failure due to inadequate secretion of endogenous growth hormone (GH) and meet **ALL** of the following criteria?

- Therapy is prescribed by or in consultation with an endocrinologist
- The patient has open epiphyses (as confirmed by radiograph of the wrist and hand), OR the patient has not completed prepubertal growth

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?

- The patient has an annual growth velocity of at least 2 cm compared with what was observed from the previous year
- The patient is near the terminal phase of puberty and has an annual growth velocity of at least 1 cm compared with what was observed from the previous year

If yes, **approve for 12 months by HICL or GPI-10.**

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SOMATROGON-GHLA

RENEWAL CRITERIA (CONTINUED)

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 **SOMATROGON-GHLA (Ngenla)** 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. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
- C. You have open epiphyses (end part of long bone) as confirmed by radiograph (type of imaging test) of the wrist and hand, OR you have not completed prepubertal growth
- D. You meet ONE of the following:
 - 1. Your annual growth velocity (rate of growth) is at least 2 cm compared with what was observed from the previous year
 - 2. Your annual growth velocity is at least 1 cm compared with what was observed from the previous year if you are near the terminal (final) phase of puberty
- E. Renewal request for Ngenla will NOT be approved for athletic enhancement, anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

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 Ngenla.

REFERENCES

- Ngenla [Prescribing Information]. Pfizer Ireland Pharmaceuticals: Ringaskiddy, Cork, Ireland; June 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 09/01/23

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P&T Approval: 04/21