



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MECASERMIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MECASERMIN	INCRELEX	33207		GPI-10 (3016004500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have **ONE** of the following diagnoses?
 - Severe primary IGF-1 deficiency
 - Growth hormone (GH) gene deletion (not growth hormone-deficient short stature) **AND** have neutralizing antibodies to GH

If yes, continue to #2.

If no, do not approve.

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

2. Does the patient meet **ALL** of the following criteria?
 - The patient is 2 years to less than 18 years of age
 - The requested medication is prescribed by or given in consultation with a pediatric endocrinologist or a pediatric nephrologist
 - Height standard deviation score ≤ -3.0
 - Basal IGF-1 standard deviation score ≤ -3.0
 - Normal or elevated growth hormone (GH), [serum growth hormone level of $\geq 10\text{ngm/mL}$ to at least two stimuli (insulin, levodopa, arginine, clonidine, or glucagon)]
 - The patient's epiphyses (bone growth plates) open (as confirmed by radiograph of the wrist and hand)

If yes, **approve by HICL or GPI-10 for 6 months up to a maximum dose of 9 vials per month.**

If no, do not approve.

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 **MECASERMIN (Increlex)** requires the following rule(s) be met for approval:

- A. You have **ONE** of the following diagnoses:
 1. Severe primary insulin growth-like factor 1 deficiency (IGF-1: hormone levels that promote normal bone and tissue growth and development are extremely low or undetectable in the blood)
 2. Growth hormone gene deletion (not growth hormone-deficient short stature) and developed neutralizing antibodies to growth hormone

(Initial denial text continued on the next page)

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INITIAL CRITERIA (CONTINUED)

- B. You are 2 years or less than 18 years of age
- C. The requested medication is prescribed by or given in consultation with a pediatric endocrinologist (hormone doctor) or pediatric nephrologist (kidney doctor)
- D. You have a height standard deviation score less than or equal to -3.0, basal IGF-1 (insulin growth-like factor 1) standard deviation score less than or equal to -3.0, and normal or elevated growth hormone [serum growth hormone level of greater than or equal to 10ngm/mL to at least 2 stimuli (insulin, levodopa, arginine, clonidine or glucagon)]
- E. Your bone growth plates (epiphyses) are open (as confirmed by radiograph of the wrist and hand)

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. Has the patient shown a response in the first 6 months of IGF-1 therapy (i.e., increase in height, increase in height velocity)?

If yes, **approve by HICL or GPI-10 for 12 months up to a maximum dose of 9 vials per month.**

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 **MECASERMIN (Increlex)** requires the following rule(s) be met for renewal:

- A. You have shown a response in the first 6 months of insulin growth-like factor-1 (IGF-1) therapy (increase in height, increase in height velocity)

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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RATIONALE

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

REFERENCES

- Increlex [Prescribing Information]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; December 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/20

Created: 02/06

Client Approval: 03/20

P&T Approval: 04/20