

**Idaho Medicaid – Therapeutic Criteria for Increlex  
Approved by Pharmacy & Therapeutics Committee on April 19, 2013**

<b>Diagnoses and Criteria</b>
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**Children with Severe Primary IGF-1 (Insulin-Like Growth Factor) Deficiency  
OR  
Children with growth hormone gene deletion who have developed neutralizing  
antibodies to growth hormone.**

**Criteria**

- Height standard deviation  $\leq -3.0$  AND
- Basal IGF-1 standard deviation score  $\leq -3.0$  AND
- Normal or elevated growth hormone levels (for children with primary IGF-1 deficiency).

**Increlex should NOT be used for:**

- Secondary forms of IGF-1 deficiency including growth hormone deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacologic doses of anti-inflammatory steroids

**Thyroid and nutritional deficiencies must be corrected before initiating Increlex treatment.**

**Increlex is NOT a substitute for growth hormone for growth hormone approved indications.**

**Contra-Indications**

- Active or suspected malignancy.
- Closed epiphyses.
- Children less than 2 years of age (safety and efficacy has not been established).

**Dosage**

- Recommended starting dose is 0.04-0.08mg/kg/dose given subcutaneously twice daily
- Maximum dose is 0.12mg/kg/dose given subcutaneously twice daily. Higher mg/kg doses have not been studied and should not be used due to potential hypoglycemic effects.

### **Medical Necessity Documentation for Growth**

#### **For initial approval only**

Height 3 or more standard deviations below mean of normal for age and sex

#### **For initial approvals AND annual renewals (all of the following must be met)**

Increase in height of at least 2 cm over the past year

AND

Bone age: female < 14 years and male < 16 years. The radiology report should include standard deviation and/or confidence intervals

AND

Documentation of open epiphyses within the previous six months

AND

No expanding lesion or tumor diagnosis

AND

Chronological age < 18 years.

### **Documentation Required for Prior Authorization Requests**

Physician notes documenting the diagnosis AND

Endocrinologist is initiating the growth hormone therapy AND

Most recent endocrinologist's office visit note AND

Current growth chart AND

Most recent bone age

### **REFERENCES**

Increlex Prescribing information. Tersica, Inc., Brisbane, CA. Version 2/16/2011.

Corporate Medical Policy: Treatment for Severe Primary IGF-1 Deficiency. Blue Cross Blue Shield, 2011.

Medical Policy Statement: Increlex. CareSource, 2011.

Texas Medicaid: Criteria for Outpatient Use Guidelines for Increlex, 2012.

Summary Growth Factors. Magellan Medicaid Administration. Last revised March 2012.

Initial approval by Idaho Medicaid's Pharmacy & Therapeutics Committee – 05/11/2012  
Reaffirmed by Idaho Medicaid's P&T Committee with no changes – 4/19/13