

**Idaho Medicaid – Therapeutic Criteria for Increlex
Updated 05-18-2017**

Diagnoses and Criteria

**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

- Baseline height (prior to starting therapy): $\leq 3^{\text{rd}}$ percentile for age/sex
- Basal IGF-1 standard deviation score ≤ -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.

Required Documentation for Growth

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

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 and 4/18/14
Revised: 5/18/17