BlueCross BlueShield Arizona

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| **PHARMACY COVERAGE GUIDELINES** | | **ORIGINAL EFFECTIVE DATE:** | **11/15/2018** |
| **SECTION: DRUGS** | | **LAST REVIEW DATE:** | **11/18/2021** |
| | | **LAST CRITERIA REVISION DATE:** | **11/18/2021** |
| | | **ARCHIVE DATE:** | |

# INCRELEX® (mecasermin) subcutaneous solution

**Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.**

**This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.**

**The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.**

**The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.**

**State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.**

**Pharmacy Coverage Guidelines are subject to change as new information becomes available.**

**For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.**



This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

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**SECTION: DRUGS**

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## INCRELEX® (mecasermin) subcutaneous solution

**Criteria**:

- **Criteria for initial therapy:** Increlex (mecasermin) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Endocrinologist

2. Individual is 2 through 17 years of age

3. A confirmed diagnosis of **ONE** of the following:
    a. **Individual with growth failure from severe primary Insulin-like growth factor-1 deficiency (IGFD)** and **ALL** of the following:
        i. Height is 3 standard deviations or more below normal for age and sex of the individual
        ii. Basal IGF-1 level is 3 standard deviations or more below normal for age and sex of the individual
        iii. Normal or elevated growth hormone (GH) level

    b. **Individual with growth hormone gene deletion who have developed neutralizing antibodies to growth hormone** and **ALL** of the following:
        i. Growth hormone levels are normal or low
        ii. IGF-1 levels are on the lowest 25% of reference laboratory's range

4. **ALL** of the following baseline tests have been completed before initiation of treatment with continued monitoring as clinically appropriate:
    a. Funduscopic examination
    b. Pre-prandial glucose

5. There is documentation of open epiphyses on last bone radiograph

6. There is no concurrent use with any growth hormone product

7. Individual does not have renal impairment or hepatic impairment

8. There is **NO** evidence of secondary forms of IGF deficiency (e.g., growth hormone deficiency, malnutrition, hypothyroidism, chronic treatment with systemic anti-inflammatory steroids)

9. There are **NO** FDA-label contraindications, such as:
    a. Active or suspected malignant neoplasia
    b. History of malignancy
    c. Growth promotion in patients with closed epiphyses (growth plates)

**Initial approval duration**: 12 months

## INCRELEX® (mecasermin) subcutaneous solution

- **Criteria for continuation of coverage (renewal request):** Increlex (mecasermin) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Endocrinologist

  2. Individual's condition has responded while on therapy
     a. Response is defined as:
        i. Final adult height has not been reached
        ii. Individual's height has increased at least 2 cm total growth in one year over the previous year (*previous year and current year height values must be submitted with date they were done*)

  3. Criteria for renewal or continuation includes **ALL** of the following:
     a. There is documentation of the expected goal adult height
     b. The epiphyses are still open

  4. Individual has been adherent with the medication

  5. Individual has not developed any contraindications or other significant adverse drug effects that may exclude continued use
     a. Contraindications as listed in the criteria for initial therapy section
     b. Significant adverse effect such as:
        i. Severe hypoglycemia or persistent hypoglycemia despite increased food intake, rescue medication, and dose adjustment of Increlex
        ii. Intracranial Hypertension
        iii. Severe Lymphoid Tissue Hypertrophy (tonsillar/adenoidal hypertrophy)
        iv. Slipped Capital Femoral Epiphysis (SCFE)
        v. Progression of Scoliosis
        vi. Evidence of benign or malignant neoplasm
        vii. Benzyl alcohol reaction – "gasping syndrome"

  6. There is no concurrent use with any growth hormone product

  7. Individual does not have renal impairment or hepatic impairment

  **Renewal duration**: 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

  1. **Off-Label Use of a Non-cancer Medications**

  2. **Off-Label Use of a Cancer Medication for the Treatment of Cancer without a Specific Coverage Guideline**

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# INCRELEX® (mecasermin) subcutaneous solution

## Description:

Increlex (mecasermin) is an injectable solution of human insulin-like growth factor-1 (IGF-1) produced by recombinant DNA technology. Increlex is used for the treatment of growth failure in children with severe primary IGF-1 deficiency, also referred to as primary IGFD. Primary IGFD is a growth hormone (GH)-resistant state characterized by lack of IGF-1 production in the presence of normal or elevated levels of endogenous GH.

These children have normal or elevated levels of growth hormone but due a deficiency of IGF-1, are unable to utilize the growth hormone resulting in extremely short stature. Increlex is also used in children with a growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH. It is not a substitute for GH for approved GH indications.

Severe Primary IGFD includes classical and other forms of growth hormone insensitivity. Patients with Primary IGFD may have mutations in the GH receptor (GHR), post-GHR signaling pathway including the IGF-1 gene. However, they are not GH deficient, and therefore, they are not expected to respond adequately to exogenous GH treatment.

Increlex is not intended for use in subjects with secondary forms of IGF-1 deficiency, such as GH deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacologic doses of anti-inflammatory steroids. Thyroid and nutritional deficiencies should be corrected before initiating Increlex treatment. Increlex is not a substitute for GH treatment.

## Definitions:

Severe primary IGF-1 deficiency is defined by:
- Height standard deviation score less than or equal to –3.0 for age and sex of the individual
- Basal IGF-1 standard deviation score less than or equal to –3.0 for age and sex of the individual
- Normal or elevated growth hormone

## Resources:

Increlex (mecasermin) product information, revised by manufacturer Ipsen Biopharmaceuticals, Inc. 12-2019 Available at DailyMed http://dailymed.nlm.nih.gov. Accessed September 21, 2021.

Richmond EJ, Rogol AD. Growth hormone insensitivity syndromes. In: UpToDate, Geffner ME, Hoppin AG (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Accessed September 21, 2021.

Richmond EJ, Rogol AD. Growth hormone treatment for idiopathic short stature. In: UpToDate, Geffner ME, Hoppin AG (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Accessed September 21, 2021.