increlex®
(mecasermin) injection 10 mg

INCRELEX® CODING

NDC#: 15054-1040-05

INCRELEX® is supplied as a 10 mg per mL sterile solution in multiple dose glass vials (40 mg per vial)

HCPCS Code	Description
J2170	Injection, Mecasermin, 1 mg

Potential Diagnosis Codes for Growth Failure in Children With Severe Primary IGF-1 Deficiency

Please note that the diagnosis codes listed below are potential examples that are sometimes used for coding growth failure in children with severe primary IGF-1 deficiency. Coding must be selected by the provider as appropriate based on diagnosis and treatment for the individual patient in each case.

ICD-10-CM Code[a]	ICD-10-CM Description
E34.3	Short Stature Due to Endocrine Disorder
R62.52	Short Stature (child)
E23.0	Hypopituitarism

[a]Source: ICD10Data.com

INCRELEX® is distributed through a closed network of specialty pharmacies, including Accredo®, BriovaRx®, CVS Health Specialty Pharmacy, and Walgreens Specialty Pharmacy.

INDICATION

INCRELEX® (mecasermin) is indicated for the treatment of growth failure in pediatric patients aged 2 years and older with severe primary IGF-1 deficiency* (IGFD), or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH.

Limitations of use: INCRELEX is not a substitute to GH for approved GH indications. INCRELEX is not indicated for use in patients with secondary forms of IGFD, such as GH deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacologic doses of anti-inflammatory corticosteroids.

*Severe primary IGFD is defined by height standard deviation score ≤ -3.0 and basal IGF-1 standard deviation score ≤ -3.0 and normal or elevated GH.

IMPORTANT SAFETY INFORMATION

Contraindications

- **Hypersensitivity** to mecasermin (rhIGF-1), any of the inactive ingredients in INCRELEX or who have experienced a severe hypersensitivity to INCRELEX. Allergic reactions have been reported, including anaphylaxis requiring hospitalization.
- **Intravenous Administration**
- **Closed Epiphyses**
- **Malignant Neoplasia** in pediatric patients with malignant neoplasia or a history of malignancy

Warnings and Precautions

- **Hypoglycemia:** INCRELEX should be administered 20 minutes before or after a meal or snack and should not be administered when the meal or snack is omitted. Glucose monitoring and INCRELEX dose titration are recommended until a well-tolerated dose is established and as medically indicated.
- **Intracranial Hypertension:** Funduscopic examination is recommended at the initiation of and periodically during the course of therapy.
- **Lymphoid Tissue Hypertrophy:** Patients should have periodic examinations to rule out potential complications.

Please see next page for additional Important Safety Information and accompanying Full Prescribing Information.

MAKE A DIFFERENCE

For Patients With Severe Primary IGFD From the Start...

IPSEN CARES Serves as a Central Point of Contact between patients/caregivers, healthcare providers, insurance companies, and specialty pharmacies

IPSEN CARES™
Coverage, Access, Reimbursement & Education Support

The IPSEN CARES Program is staffed by dedicated Patient Access Specialists who can assist in a variety of ways:

- Benefits Verification
- Prior Authorization (PA)/Appeals Information
- **Eligible* Patients Can Pay As Little As $0 Per Prescription through the Ipsen Cares copay assistance program**
- Patient Assistance Program (PAP) Determination
- Referrals to Specialty Pharmacy Network
- Billing and Coding Information
- Communication With Providers and Patients
- Injection Training

For more information, please visit www.ipsencares.com or call 1-866-435-5677
Monday – Friday 8:00 AM – 8:00 PM ET

*Patient Eligibility & Terms and Conditions: Patients are not eligible for copay assistance through IPSEN CARES® if they are enrolled in any state or federally funded programs, including, but not limited to, Medicare Part B, Medicare Part D, Medicaid, Medigap, VA, DoD, or TRICARE (collectively, "Government Programs"), or where prohibited by law. Patients residing in Massachusetts, Minnesota, Michigan, or Rhode Island can only receive assistance with the cost of Ipsen products but not the cost of related medical services (injection). Patients receiving assistance through another assistance program or foundation, free trial, or other similar offer or program, are not eligible for the copay assistance program during the current enrollment year.

Cash-pay patients are eligible to participate. "Cash-pay" patients are defined for purposes of this program as patients without insurance coverage or who have commercial insurance that does not cover Increlex®. Medicare Part D enrollees who are in the prescription drug coverage gap ("donut hole") are not considered cash-pay patients and are not eligible for copay assistance through IPSEN CARES®. For patients with commercial insurance that are not considered to be cash-pay patients, the maximum copay benefit amount per prescription is an amount equal to the difference between the annual maximum copay benefit of $12,000 and the total amount of copay benefit provided to the patient in the Increlex® Copay Program. For cash-pay patients, the maximum copay benefit amount per prescription is $1,000, subject to the annual maximum of $12,000 in total. Patient pays any amount greater than the maximum copay savings amount per prescription.

Patient or guardian is responsible for reporting receipt of copay savings benefit to any insurer, health plan, or other third party who pays for or reimburses any part of the prescription filled through the program, as may be required. Additionally, patients may not submit any benefit provided by this program for reimbursement through a Flexible Spending Account, Health Savings Account, or Health Reimbursement Account. Ipsen reserves the right to rescind, revoke, or amend these offers without notice at any time. Ipsen and/or RxCrossroads by McKesson are not responsible for any transactions processed under this program where Medicaid, Medicare, or Medigap payment in part or full has been applied. Data related to patient participation may be collected, analyzed, and shared with Ipsen, for market research and other purposes related to assessing the program. Data shared with Ipsen will be de-identified, meaning it will not identify the patient. Void outside of the United States and its territories or where prohibited by law, taxed, or restricted. This program is not health insurance. No other purchase is necessary.

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

- **Slipped Capital Femoral Epiphysis:** Carefully evaluate any pediatric patient with the onset of a limp or hip/knee pain during INCRELEX therapy.
- **Progression of Scoliosis:** Patients with a history of scoliosis, treated with INCRELEX, should be monitored.
- **Malignant Neoplasia:** There have been postmarketing reports of malignant neoplasia in pediatric patients who received treatment with INCRELEX. The tumors were observed more frequently in patients who received INCRELEX at higher than recommended doses or at doses that produced serum IGF-1 levels above the normal reference ranges for age and sex. Monitor all patients receiving INCRELEX carefully for development of neoplasms. If malignant neoplasia develops, discontinue INCRELEX treatment.
- **Risk of Serious Adverse Reactions in Infants due to Benzyl Alcohol Preserved Solution:** Serious and fatal adverse reactions including "gasping syndrome" can occur in neonates and infants treated with benzyl alcohol-preserved drugs. Use of INCRELEX in infants is not recommended.

Adverse Reactions

Common adverse reactions include hypoglycemia, local and systemic hypersensitivity, and tonsillar hypertrophy.

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