

IPSEN CARES™

Coverage, Access, Reimbursement & Education Support

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, 1mg

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 may be appropriate 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-9-CM Code ¹	ICD-9-CM Description	ICD-10-CM Code ¹	ICD-10-CM Description
259.4	Dwarfism, Not Elsewhere Classified Dwarfism: NOS, Constitutional	E34.3	Short Stature Due to Endocrine Disorder Constitutional Short Stature Laron-type Short Stature
783.43	Short Stature Growth Failure Growth Retardation	R62.52	Short Stature (child) Lack of Growth Physical Retardation Short Stature NOS

As of March 2016, INCRELEX® is distributed through a closed network of specialty pharmacies, including Accredo®, BriovaRx® (formerly OptumRx), CVS Health Specialty Pharmacy (formerly CVS/Caremark), and Walgreens Specialty Pharmacy.

INCRELEX® INDICATION

INCRELEX® is indicated for the treatment of growth failure in children with severe primary IGF-1 deficiency (IGFD), or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH. Severe Primary IGFD is defined by height standard deviation score ≤ -3.0 and base IGF-1 standard deviation score ≤ -3.0 and normal or elevated GH.

INCRELEX® is not intended for use in subjects with secondary forms of IGFD, 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.

Limitations of use: INCRELEX® is not a substitute to GH for approved GH indications. INCRELEX has not been studied in children <2 years of age. It is recommended that you verify with your local payer(s) on their policies to determine INCRELEX® coverage.

SELECT IMPORTANT SAFETY INFORMATION

Contraindications:

- Presence of active or suspected malignancy
- Hypersensitivity to mecasermin (rhIGF-1) or any of the inactive ingredients in INCRELEX®
- Intravenous administration
- Closed epiphyses

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

¹Source: 2015 ICD-9-CM for Hospitals, Volumes, 1, 2 & 3. Professional Edition. 2016 ICD-10-CM Code Book

MAKE A DIFFERENCE

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

Ipsen is fully dedicated to helping patients and ensuring that they are able to access the medications that are critical to managing their conditions. To embody this commitment, Ipsen is proud to present IPSEN CARES™ (Coverage, Access, Reimbursement & Education Support).

Phone: 1-866-435-5677 • Fax: 1-888-525-2416 • Hours: 8:00 am to 8:00 pm ET/Monday - Friday

Reimbursement Support

- Benefits Verification – determines patient's coverage, restrictions (if applicable) and copayment/coinsurance amounts
- Prior Authorization Information – collects information required to submit documents for prior authorization, provide recommendations for next steps based off conversations with patient's insurance company
- Prior Authorization Appeals Information – collects information required to submit documents for appeals process, provide recommendations for next steps based off conversations with patient's insurance company

Patient Assistance for Eligible* Patients

- Patient Assistance Program (PAP) – provides free medication to eligible* patients

Product Distribution

- Referrals to Specialty Pharmacy Network – determines which in-network pharmacy is best for patient per insurance requirements and triage referrals. Follow-up phone calls are placed 24 hours after referral is triaged to confirm receipt and shipment date

Patient Support

- Injection Training Requests – triages requests for injection training and follow up with phone calls to confirm injection training and shipment date
- Billing & Coding Assistance – assists with Billing & Coding questions to those calling into the IPSEN CARES™ program
- 360-degree communication with providers and patients – makes proactive, outbound calls to both providers and patients with status updates regarding their IPSEN CARES™ enrollment, benefits verification results, prior authorization status, dispense date, etc.

SELECT IMPORTANT SAFETY INFORMATION - Continued

Warnings and Precautions:

- Hypoglycemic effects: 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
- Hypersensitivity: Allergic reactions have been reported, including anaphylaxis requiring hospitalization
- Intracranial hypertension: Funduscopic examination is recommended at the initiation of and periodically during the course of therapy
- Tonsillar/adenoidal hypertrophy: Patients should have periodic examinations to rule out potential complications
- Slipped capital femoral epiphysis: Evaluate any child with onset of limp or hip/knee pain
- Progression of scoliosis: Monitor any child with scoliosis

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

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

*Not all patients are eligible. Please call IPSEN CARES™ at 1-866-435-5677 to evaluate eligibility.