Questions? Call IPSEN CARES at 866.435.5677

increlex®
(mecasermin [rDNA origin] injection)

INCRELEX IPSEN CARES Enrollment Form

Please fill out form completely and
FAX BACK TO 888.525.2416

☐ Benefits Investigation and Drug Coverage ☐ Prior Authorization Support (If Needed) ☐ Financial Assistance Assessment ☐ Injection Training

(Please complete requirements for each section below.)

PATIENT

Patient name (first & last)_____
Date of birth (MM/DD/YYYY) _____/ _____ / _____ ☐ Male ☐ Female
Patient address _____
City_____ State_____ Zip_____
Home phone (___) _____ Other phone (___) _____
Social Security number _____

PARENT/GUARDIAN

Parent/Guardian name_____
Social Security number _____
Email address_____
Home phone (___) _____ Other phone (___) _____
May we leave a phone or email message referring to Increlex? ☐ Yes ☐ No
Parent/ Guardian language preference ☐ English ☐ Spanish ☐ Other_____

PHARMACY INSURANCE

Is patient insured? ☐ Yes ☐ No Does patient have secondary insurance? ☐ Yes ☐ No
Primary insurance co._____
Insurance co. phone #_____
Subscriber_____ Policy ID #_____
Policy/Employer/Group # _____

Secondary insurance co. _____
Insurance co. phone # _____
Subscriber_____ Policy ID # _____
Policy/Employer/Group # _____

Important: Please send a copy of insurance cards – front and back. Include both medical and pharmacy cards, if available.

PRESCRIBER

Prescriber name_____
DEA #_____ State license # _____
Tax ID # _____ NPI # _____
Medicaid provider # _____
Medicare PTAN # _____
Office/Institution _____
Specialty ☐ Pediatric Endocrinologist ☐ Other:_____

Street Address _____
_____
City_____ State_____ Zip_____
Office contact and title_____
Phone (___) _____ Fax (___) _____
Email address_____
Preferred method of contact ☐ Phone ☐ Fax ☐ Email

PHARMACY & SHIPMENT

Has a current prescription been submitted directly to the specialty pharmacy? ☐ Yes ☐ No
If yes, to which specialty pharmacy? ☐ Accredo ☐ CVS/Caremark ☐ Optum RX ☐ Walgreens
Preferred delivery location ☐ Patient's home ☐ Prescriber's office
☐ Other _____
Special shipping instructions _____

DIAGNOSIS

Based on my evaluation, this patient's diagnosis is severe Primary IGF-1 deficiency (IGFD):

☐ Yes ☐ If no, please provide the other diagnosis_____

☐ 783.43/R62.52 Short Stature/Growth Failure
☐ Other _____ Date of IGFD diagnosis _____/_____/_____
ICD9/10 Code

Important: Please remember to include both a diagnosis description and an ICD-9/10 code.

STATEMENT OF MEDICAL NECESSITY & PRIOR AUTHORIZATION INFORMATION

Have other products been used to treat IGFD for this patient? ☐ Yes ☐ No
Product _____ Date of last injection_____/ _____ / _____
List allergies_____ ☐ NKDA ☐ SP
Patient Height_____Weight_____kg
Most Recent IGF-1 Test Results_____Date of Most Recent IGF-1 Test_____

Other information supporting medical necessity

Increlex® (mecasermin [rDNA origin] injection) 40 mg/4 mL vial

PRESCRIPTION

Has the patient previously been on Increlex therapy? ☐ No ☐ Yes. If yes, last administered dose _____ mg/kg on _____ (MM/DD/YYYY)

Select a weight-based initial dosage	☐ 0.04 mg/kg ☐ 0.05 mg/kg ☐ 0.06 mg/kg ☐ 0.07 mg/kg ☐ 0.08 mg/kg	_____(kg weight) **X** _____**mg/kg** = _____(Dose) **mg X 10** = **inject Subcutaneous** _____ **BID** (units)

Quantity: _____ Number of refills: _____ Syringes for injection ☐ 0.5 cc_____ Qty ☐ 1 cc_____ Qty ☐ Dispense as Written

Dosing over 0.12 mg/kg BID has not been evaluated, and due to potential hypoglycemic effects, patients should not be dosed over 0.12 mg/kg BID.

PRESCRIBER ATTESTATION:

By signing below, I certify that the above therapy is medically necessary and that I have received the necessary authorization to release the above-referenced information and medical and/or patient information relating to Increlex therapy to Ipsen and its agents or contractors for the purpose of seeking reimbursement for Increlex therapy, assisting in initiating or continuing Increlex therapy, and/ or evaluating the patient's eligibility for Ipsen's patient support programs administered by IPSEN CARES. I authorize Ipsen to be my agent, to forward the above prescription, by fax or other mode of delivery, to the pharmacy chosen on behalf of the named patient. Where free starter therapy is sent to my office, I certify that the Product will be used for the above patient, and neither the patient nor any third party will be charged for such product. If named patient does not return for therapy, product will be returned to Ipsen.

_____ _____
Prescriber Signature Date

Scroll down for Indication and Important Safety Information.

Prescription is valid only if received by fax or mail. Special note: New York prescribers, please submit prescription on an original NY State prescription blank.

Please fill out form completely and fax back to 888.525.2416

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Patient Authorization

Please fax the signed form to IPSEN CARES at the number above or send the form to: **IPSEN CARES Program**
Ipsen Biopharmaceuticals, Inc.
120 Weston Oaks Court
Cary, NC 27513

Patient Authorization and Signature—IPSEN CARES Program

I authorize my healthcare providers (including those pharmacies that may receive my prescription for Increlex) to disclose personal health information (PHI) about me, including health information relating to my medical condition, treatment, and insurance coverage to Ipsen Biopharmaceuticals Inc., its affiliates, and agents who have been hired to administer the Ipsen Coverage, Access, Reimbursement & Education Support (CARES) program on its behalf (collectively, "Ipsen") in order for Ipsen to: (1) enroll me in IPSEN CARES; (2) establish my benefit eligibility and potential out-of-pocket costs for Increlex; (3) communicate with my healthcare providers and health plans about my treatment plan; (4) provide support services including patient education and financial assistance for Increlex; (5) help to get Increlex shipped to me; (6) evaluate the effectiveness of Ipsen's patient support programs and conduct market analysis, including aggregating my PHI with other data for such analyses; (7) facilitate my participation in the Increlex Copay Assistance Program and other Increlex patient programs that I have elected to receive information about as indicated below; and (8) solicit my opinions about IPSEN CARES services.

I understand that once my PHI has been disclosed to Ipsen, it is no longer protected by federal privacy laws and Ipsen may re-disclose it; however, Ipsen has agreed to protect my PHI by using and disclosing it only for the purposes described above or as required by law. I understand that my healthcare providers may receive remuneration from Ipsen in exchange for my PHI and/or for any therapy support services provided to me.

I may revoke (cancel) this Authorization at any time by mailing a letter requesting such revocation to: IPSEN CARES, 120 Weston Oaks Court, Cary, NC 27513, or by calling 866-435-5677. Canceling this Authorization will end my consent to further disclosure of my PHI and my receipt of the services, but will not affect my healthcare providers' use and disclosure of PHI in reliance on this authorization before they receive notice of my cancellation. This Authorization expires one year after the date I sign it below. I understand that I will receive a copy of the signed Authorization. I understand that I may refuse to sign this authorization and if I do not sign it, my enrollment in and eligibility for health plan benefits and treatment (including the receipt of Increlex) and payment for treatment will not be affected, but I will not have access to the IPSEN CARES program and other service described above.

Patient Name: _____ Parent/Legal Guardian Name:* _____

Relationship to Patient: _____

Signature: _____ Date: _____

Additional Product and Support Information

☐ In addition to participating in the IPSEN CARES program above, I would also like to receive information from Ipsen, which may include marketing and educational material about Increlex and programs that support patients with severe Primary IGF-1 deficiency. I understand that I do not have to sign this section of the form in order to participate in the IPSEN CARES program and that I may revoke my authorization to receive additional product information at any time. By signing below, I agree that Ipsen and its agents may use and disclose my personal information (including name, address, phone number, and/or email of the parent/caregiver) to provide these services and Ipsen may also contact me to solicit my opinions regarding Increlex and Ipsen's products and services. I understand that my cell phone carrier's standard rates may apply for calls to my cell phone. This authorization is valid until December 31, 2020. I may revoke this authorization by calling 866.435.5677 or sending a request in writing to: IPSEN CARES, 120 Weston Oaks Court, Cary, NC 27513.

Patient Name: _____

Parent/Legal Guardian Name:* _____ Relationship to Patient: _____

Signature: _____ Date: _____

*Please provide name of parent or legal guardian, if patient is under 18 years of age.

IPSEN CARES
Coverage, Access, Reimbursement & Education Support

Scroll up for Increlex Patient Indication and Important Safety Information.

Indication and Important Safety Information

Who is INCRELEX® for?

INCRELEX is used to treat children who are very short for their age because their bodies do not make enough IGF-1. This condition is called severe primary IGF-1 deficiency. INCRELEX should not be used for other causes of growth failure and should not be used instead of growth hormone.

Important Safety Information

Who should not use INCRELEX?

Your child should not take INCRELEX if your child: has finished growing (the growth plates at the end of the bones are closed), has cancer, OR is allergic to mecasermin or any of the inactive ingredients in INCRELEX. INCRELEX has not been studied in children under 2 years of age and should never be used in newborns. **Your child should never receive INCRELEX through a vein.**

Before your child takes INCRELEX, you should tell your child's doctor about:

- All of your child's health conditions, including: diabetes, kidney problems, liver problems, allergies, scoliosis (curved spine), pregnancy, or breast-feeding.
- **All the medicines (prescription and nonprescription), vitamins, and herbal supplements your child takes, especially insulin or other anti-diabetes medicines, which may require dose adjustment of these medicines.**

What are possible side effects of INCRELEX (some of which can be serious)?

- **Low blood sugar (hypoglycemia).** Only give your child INCRELEX right before or right after (20 minutes on either side of) a snack or meal to reduce the chances of hypoglycemia. Signs include dizziness, tiredness, restlessness, hunger, irritability, trouble concentrating, sweating, nausea, and fast or irregular heartbeat. Do not give your child INCRELEX if your child is sick or cannot eat. **Severe hypoglycemia may cause unconsciousness, seizures, or death.** People taking INCRELEX should avoid participating in high risk activities (such as driving) within 2 to 3 hours after an INCRELEX injection.
- **Allergic reactions.** Your child may have a mild or serious allergic reaction with INCRELEX. Call your child's doctor right away if your child gets a rash or hives. If hives do occur, they generally appear minutes to hours after the injection as an itchy, raised skin reaction, pale in the middle with a red rim around them, and may sometimes occur at numerous places on the skin. Get medical help immediately if your child has trouble breathing or goes into shock, with symptoms like dizziness, pale, clammy skin, and/or passing out.
- **Increased pressure in the brain (intracranial hypertension).** INCRELEX, like growth hormone, can sometimes cause a temporary increase in pressure within the brain. Symptoms include persistent headache, blurred vision, and nausea with vomiting.
- **Enlarged tonsils.** Signs include: snoring, difficulty breathing or swallowing, sleep apnea (a condition where breathing stops briefly during sleep), or fluid in the middle ear.
- **A bone problem called slipped capital femoral epiphysis.** This happens when the top of the upper leg (femur) slips apart from the rest of the bone. Seek immediate medical attention if your child develops a limp or has hip or knee pain.
- **Worsened scoliosis** (caused by rapid growth).
- **Injection site reactions including:** swelling, loss of fat, increase of fat, pain, redness, or bruising. This can be avoided by changing/rotating the injection site at each injection.

Your child's doctor is your primary source of information about treatment. Please click here for full Prescribing information for Increlex.

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You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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Indication and Important Safety Information

Indication

INCRELEX® (mecasermin [rDNA origin] injection) 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 basal 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.

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

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 click here for full Prescribing Information for Increlex

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