



Statement of Medical Necessity

Please fill out form completely and
FAX BACK TO 888.525.2416

PATIENT INFORMATION SECTION:

Date _____
 Patient Name (First & Last) _____
 Date of Birth _____ Gender Male Female
 Patient Address _____
 City _____ State _____ ZIP _____
 Parent/Legal Guardian _____
 Email Address _____
 Home Phone _____ Work Phone _____
 Other Phone _____
 Preferred Language _____

INSURANCE INFORMATION SECTION: Attach copy of front and back of patient's primary and secondary insurance cards

Is patient insured? Yes No Does patient have secondary insurance? Yes No
 Primary Insurance Co. _____ Policy/Employer/Group # _____
 Insurance Co. Phone # _____ Subscriber ID _____
 Subscriber _____ Employer _____

DIAGNOSIS SECTION:

Based on my evaluation, this patient's diagnosis is severe Primary IGFD:

YES NO

Date of Diagnosis _____

INCRELEX® (mecasermin [rDNA origin] injection) is indicated for the long-term treatment of growth failure in children with severe Primary IGF-1 deficiency (Primary 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 growth hormone (GH)

Please see full indication on back of form.

MEDICAL ASSESSMENT SECTION:

For your patients with severe Primary IGFD, would you like prior authorization or appeal assistance if it becomes necessary? Yes No

IGF-1 Test Result _____ Lab Reference Range _____ age/sex

Thyroid Function Test Result Normal Abnormal (please explain below) _____

GH Stimulation Test _____ Agent _____ Peak _____

Has growth hormone been tried on this patient? Agent(s) _____
 Result(s) _____

Other medications tried and failed _____

Current information as of most recent evaluation (Date) _____

Height (cm) _____ Height (%) _____

Weight (kg) _____ Growth Velocity _____ cm/yr

Chronological Age _____ years _____ mos. Bone Age _____ years _____ mos.

Date of Hand X-Ray _____ Predicted Adult Height _____ cm

Epiphyses Open? Yes No

Date of next follow-up visit _____

PRESCRIBER INFORMATION SECTION:

Prescriber Name _____

DEA# _____ St Lic# _____

Tax ID# _____

Medicaid Provider # _____

NPI # _____

Specialty: Pediatric Endocrinologist Other _____

Office/Institution _____

Street Address _____

City _____ State _____ Zip _____

Office Contact _____

Phone _____ Fax _____

Email Address _____

Preferred Method of Contact Phone Fax Email

PRESCRIPTION AND PATIENT SUPPORT INFORMATION

Would you like us to provide starter therapy if patient is eligible? Yes No

Would you like to request injection training and educational support through the Ipsen Nurse Network? Yes No Ipsen Nurse Preference: _____ No Preference

If Yes, requested location for training is: Prescriber's Office Patient Home/Work Other MD Office/Clinic _____

Prescription: Increlex® (mecasermin [rDNA origin] injection) 40 mg/4mL vial First Shipment: Physician Office Patient Home

WEEK 1 (7 days)	WEEK 2 (7 days)	MAINTENANCE DOSE
_____ X 0.04mg/kg = _____ mg X 10 Kg weight Dose	_____ X 0.08mg/kg = _____ mg X 10 Kg weight Dose	_____ X 0.12mg/kg = _____ mg X 10 Kg weight Dose
= Inject SQ [†] _____ BID Units	= Inject SQ [†] _____ BID Units	= Inject SQ [†] _____ BID Units

[†]Subcutaneous

You may include a different dosing schedule using your office prescription form

Dispense as Written Dispense: _____ month supply _____ # of refills **Inject-Ease®** Yes No **Syringes for Injection** 0.5cc _____ Qty 1cc _____ Qty

The recommended starting dose of Increlex is 0.04 to 0.08 mg/kg twice daily. If well-tolerated for at least one week, the dose may be increased by 0.04 mg/kg per dose, to the maximum dose of 0.12 mg/kg given twice daily.

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 of the patient's eligibility for Ipsen's patient support programs administered by PACE. 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.

Prescriber Signature

Date

Indication and Important Safety Information

INCRELEX® (mecasermin [rDNA origin] injection) is indicated for the long-term treatment of growth failure in children with severe Primary IGF-1 deficiency (Primary 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 \leq -3.0 and
- basal IGF-1 standard deviation score \leq -3.0 and
- normal or elevated growth hormone (GH).

Severe Primary IGFD includes patients with mutations in the GH receptor (GHR), post-GHR signaling pathway, and IGF-1 gene defects; they are not GH deficient, and therefore, they cannot be 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.

INCRELEX should not be used for growth promotion in patients with closed epiphyses. INCRELEX is contraindicated in the presence of active or suspected neoplasia, and therapy should be discontinued if evidence of neoplasia develops. Intravenous administration of INCRELEX is contraindicated. INCRELEX should not be used by patients who are allergic to mecasermin (IGF-1) or any of the inactive ingredients in INCRELEX.

INCRELEX contains benzyl alcohol as a preservative, which has been associated with neurologic toxicity in neonates.

INCRELEX has not been studied in patients under 2 years old.

Slipped capital femoral epiphysis and progression of scoliosis can occur in patients who experience rapid growth.

Local or systemic allergic reactions may occur.

In clinical studies of 71 subjects with severe Primary IGFD treated for a mean duration of 3.9 years and representing 274 subject-years, no subjects withdrew from any clinical study because of adverse events.

Hypoglycemia was reported by 30 subjects (42%) at least once during their course of therapy. Of the 30 subjects reporting hypoglycemia, 14 (47%) had a history of hypoglycemia prior to treatment. Most cases were mild or moderate in severity. Five subjects had severe hypoglycemia (requiring assistance and treatment) on one or more occasion, and four subjects experienced hypoglycemic seizures/loss of consciousness on one or more occasion. The frequency of hypoglycemia was highest in the first month of treatment, and episodes were more frequent in younger children. Hypoglycemia was generally avoided when a meal or snack was consumed either shortly before or shortly after administration.

Tonsillar hypertrophy was noted in 11 subjects (15%) in the first 1 to 2 years of therapy with lesser tonsillar growth in subsequent years.

Intracranial hypertension occurred in three subjects. In two subjects, the events resolved without interruption of INCRELEX treatment. INCRELEX treatment was discontinued in the third subject and resumed later at a lower dose without recurrence.

Please see enclosed full Prescribing Information.



increlex[®]

(mecasermin [rDNA origin] injection)

Patient Authorization

Please fill out form completely and
FAX BACK TO 888.525.2416

Please fax the signed form to PACE at
the number above or send the form to:

PACE Program

Ipsen

2000 Sierra Point Parkway, Suite 400

Brisbane, CA 94005

Patient Authorization and Signature – PACE Program

I authorize my Doctor and his/her staff, my health insurer and/or specialty pharmacy to disclose personal health information (PHI) to Ipsen, its affiliates and its agents who have been hired to administer the PACE program. I understand these parties will use and/or disclose my PHI, as needed, to coordinate the receipt, payment, and proper administration of Increlex as prescribed by my Doctor. I also authorize Ipsen to use and disclose PHI it receives about me to a pharmacy or distributor that will fill my prescription and to Ipsen's agents that implement disease management programs. I understand that once my PHI is disclosed, it may no longer be protected by federal law regarding patient privacy but that PACE will protect my information and use it only for the purposes of administering the PACE program. I understand that Ipsen may also contact me to solicit my opinions about PACE services. I understand that I do not have to sign this form and that I may revoke this Authorization at any time. My refusal to sign this Authorization or a future revocation will not affect the treatment I receive from my Doctor; however, PACE may not be able to provide reimbursement assistance or find out if I am eligible for any other PACE services. This Authorization is valid until December 31, 2020. To revoke this Authorization, please call 866.435.5677 or send your request in writing to: PACE, 2000 Sierra Point Parkway, Suite 400, Brisbane, CA 94005.

I acknowledge that I would like to participate in the PACE program. I understand that by enrolling in the program, a Patient Care Liaison at PACE will contact me directly by phone or email.

Patient Name: _____

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

Signature _____ Date _____

Additional Support and Product Information

In addition to participating in the PACE program above, I would also like to receive additional support from Ipsen, which may include receiving marketing and educational information about Increlex and programs that support patients with severe Primary IGF deficiency. I understand that I do not have to sign this section of the form in order to participate in the PACE program and that I may revoke my authorization to receive additional support and product information at any time. By signing below, I agree that Ipsen and its agents may use and disclose my personal information to provide these services and Ipsen may also contact me to solicit my opinions regarding Increlex, 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. To revoke this Authorization, please call 866.435.5677 or send your request in writing to: Increlex Patient Marketing Programs, 2000 Sierra Point Parkway, Suite 400, Brisbane, CA 94005.

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.





Getting Started with PACE

INFORMATION FOR PATIENTS WHO HAVE BEEN DIAGNOSED WITH SEVERE PRIMARY IGF DEFICIENCY

Important information regarding how you will obtain your prescription for Increlex (mecasermin [rDNA origin] injection)

Ipsen is proud to present PACE, our Patient Access, Care and Education program. PACE is a comprehensive service and support program designed to address questions you may have about starting and staying on Increlex when you, or your child, have been diagnosed with severe Primary IGFD. The goal of PACE is to simplify interactions between you, your insurance company, and your doctor's office.

Our Patient Care Liaisons are at the center of PACE. Every patient is provided a personal contact— readily available with support by phone.

Helping your treatment experience go smoothly

1. Your doctor will submit a Statement of Medical Necessity (SMN) to PACE
 - If your doctor decides that Increlex is right for you, he or she will complete and submit an SMN form
 - The SMN includes your prescription for Increlex and will be faxed directly to PACE
2. A Patient Care Liaison (PCL) from PACE will contact you
 - A PCL from PACE will contact you once he or she receives the SMN from your doctor. It is important that you speak with the PCL so he or she can provide important information about insurance benefits related to your prescription. The PCL will also work with you to arrange for injection training if requested by your doctor.
 - ***Please note, your prescription for Increlex could be delayed if you do not return these calls.***
3. A specialty pharmacy will send your shipment of Increlex therapy
 - Increlex is dispensed through a limited number of specialty pharmacies. Your prescription will be sent directly to you or your doctor by the specialty pharmacy. The specialty pharmacy will coordinate shipments of your refill prescriptions as well.
 - ***The specialty pharmacy must speak with you before they can send your medication, so please return these calls promptly.***

PACE can simplify interactions with your insurance company and specialty pharmacy, help to provide you a better understanding of your condition and help your treatment experience go smoothly. If you have questions about PACE, please call **866.435.5677**.