



**Growth Hormone Antagonist
 Increlex (mecasermin) J2170, Signifor
 LAR (pasireotide) J2502
 Prior Authorization Request
 Medicare Part B Form**

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

<input type="checkbox"/>	Standard Request– (72 Hours)	<input type="checkbox"/>	Urgent Request (standard time frame could place the member's life, health or ability in serious jeopardy)
Date Requested _____			
Requestor _____ Clinic name: _____ Phone _____ / Fax _____			

MEMBER INFORMATION

*Name: _____ *ID#: _____ *DOB: _____

PRESCRIBER INFORMATION

*Name: _____ MD FNP DO NP PA *Phone: _____

*Address: _____ *Fax: _____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name: _____ Phone: _____

*Address: _____ Fax: _____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht: _____)	Frequency	End Date if known

Self-administered Provider-administered Home Infusion

Chart notes attached. **Other important information:** _____

Diagnosis: ICD10: _____ **Description:** _____

Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

New Start or Initial Request: (Clinical documentation required for all requests)

Increlex

- Child with growth failure associated with severe primary IGF-1 deficiency, as defined by:
 - Height standard deviation (SD) score less than or equal to –3.0; AND
 - Basal IGF-1 SD score less than or equal to –3.0; AND
 - Normal or elevated growth hormone (GH) levels (greater than 10 ng/ml on standard GH stimulation tests) are present;
- OR Individual with growth hormone gene deletion with the development of neutralizing antibodies to GH.

Signifor

- Diagnosis of acromegaly; AND
 - Diagnosis of acromegaly has been verified by, or in consultation with, a board-certified endocrinologist who has reviewed and verified the test results (including but not limited to: Insulin-like Growth Factor 1 levels; Oral Glucose Tolerance Test with associated Growth Hormone (GH) levels) that are indicative of a positive test; AND

Individual has had an inadequate response to surgery and/or surgery is not an option (including but not limited to, individual is an inappropriate candidate for surgical-based therapy).

OR diagnosis of Cushing's disease; AND

Diagnosis of Cushing's has been verified by, or in consultation with, a board-certified endocrinologist who has reviewed and verified the test results (including but not limited to: 24-hour urinary free cortisol (UFC) test; Dexamethasone suppression test (DST); Late-night salivary cortisol (LNSC) test) that are indicative of a positive test; AND

One of the following:

- Disease persists or recurs following pituitary surgery; OR
- Pituitary surgery is not indicated or an option.

If not, please provide **clinical rationale** for formulary exception: _____

Continuation Requests: (Clinical documentation required for all requests)

Increlex only

- Documentation is provided that growth velocity is greater than or equal to 2 cm total growth in 1 year; AND
- Documentation is provided that final adult height has not been reached.

Signifor

- Patient had an adequate response or significant improvement while on this medication.

If not, please provide clinical rationale for continuing this medication: _____

ACKNOWLEDGEMENT

Request By (Signature Required): _____ **Date:** ____ / ____ / ____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT. PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.**

Prior Authorization Group – Growth Hormone Antagonists PA

Drug Name(s):
SIGNIFOR LAR
INCRELEX

PASIREOTIDE
MECASERMIN

Criteria for approval of Prior Authorization Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Drug is being used appropriately per MCG GUIDELINES, CMS recognized compendia, authoritative medical literature, evidence-based guidelines and/or accepted standards of medical practice.
3. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.
 - If the member meets all these criteria, they may be approved by the Plan for the requested drug.
 - Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

N/A

Prescriber Restrictions:

N/A

Coverage Duration:

Approvals will be for 12 months

FDA Indications:

Increlex

- Growth delay due to insulin-like growth factor type 1 deficiency (Severe)

Signifor

- Acromegaly, In patients with an inadequate response to surgery or who are not candidates for surgery
- Cushing's syndrome, When pituitary surgery is not an option or has not been curative

Off-Label Uses:

Signifor

- Carcinoid syndrome, Inadequately controlled with first generation somatostatin analogs - Neuroendocrine tumor, Metastatic, of the digestive tract

Age Restrictions:

Safety and effectiveness of ocrelizumab have not been established in pediatric patients

Other Clinical Considerations:

N/A

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/CS/AD5F4D/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/441433/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.DoIntegratedSearch?SearchTerm=Pasireotide&fromInterSaltBase=true&UserMdxSearchTerm=%24userMdxSearchTerm&false=null&=null#



Part B Prior Authorization Guidelines

https://www.micromedexsolutions.com/micromedex2/librarian/CS/35FAD4/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/854B2C/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.DoIntegratedSearch?SearchTerm=Mecasermin&fromInterSaltBase=true&UseMdxSearchTerm=%24userMdxSearchTerm&>false=null&=null#

https://careweb.careguidelines.com/ed24/ac/ac04_122.htm

CLINICAL / CMS
ONLY