Signifor® LAR (pasireotide)
(Intramuscular)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months.
- Renewal: Prior authorization validity may be renewed every 12 months thereafter.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- **Acromegaly**
  - 60 billable units (60 mg) every 28 days
- **Cushing's disease**
  - 40 billable units (40 mg) every 28 days

III. Initial Approval Criteria [1]

Prior authorization validity is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- Confirmation that fasting plasma glucose, hemoglobin A1c, liver enzyme tests, electrocardiogram (ECG), serum magnesium and serum potassium have been evaluated prior to starting treatment; **AND**
- Patients with diabetes mellitus have stable glycemic control and are on optimized anti-diabetic treatment prior to the start of therapy; **AND**

Universal Criteria [1]

- Patient does not have severe hepatic impairment (i.e., Child-Pugh Class C); **AND**
- Patient has not received a long-acting somatostatin analog within the last 4 weeks; **AND**

Acromegaly † Φ [1,4,5,10,14]

- Patient's diagnosis is confirmed by one of the following:
  - Unequivocally elevated (age-adjusted) serum insulin-like growth factor-1 (IGF-1); **OR**
  - Equivocally elevated (age-adjusted) serum IGF-1 AND inadequate suppression of growth hormone (GH) after a glucose load; **AND**
- Patient has documented inadequate response to surgery and/or radiotherapy or it is not an option for the patient; **AND**
- Baseline GH and IGF-1 blood levels have been obtained (renewal will require reporting of current levels); **AND**
- Will not be used in combination with oral octreotide or with GH-analog (e.g., pegvisomant)

Cushing's Disease † Φ [1,9,12,13]

- Confirmed diagnosis of endogenous Cushing's disease in which the patient's hypercortisolism is not a result of chronic administration of high-dose glucocorticoids or other physiologic conditions; **AND**
- Treatment of patient's disease with pituitary surgery has not been curative OR the patient is not a candidate for pituitary surgery; **AND**
- Baseline 24-hour urinary free cortisol (UFC) level, Adrenocorticotropic hormone (ACTH), late-night salivary cortisol (LNSC), and/or serum cortisol level have been obtained (renewal will require reporting of current levels)

† FDA Approved Indication(s); **‡** Compendia Recommended Indication(s); **Φ** Orphan Drug

IV. Renewal Criteria [1]

Prior authorization validity can be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: uncontrolled hyperglycemia, diabetes, ketoacidosis, bradycardia, QT prolongation, liver test elevations (e.g., alanine aminotransferase [ALT] or aspartate aminotransferase [AST]), cholelithiasis (gallstones) and complications of cholelithiasis (e.g., cholecystitis or cholangitis), pituitary hormone (e.g., thyroid, adrenal, gonadal) deficiencies/severe adrenal insufficiency, malabsorption of dietary fats (steatorrhea, stool discoloration, loose stools, etc.), etc.; **AND**

Acromegaly [1,4,5,10]

- Disease response as indicated by an improvement in signs and symptoms compared to baseline; **AND**
  - Reduction of growth hormone (GH) from pre-treatment baseline; **OR**
  - Age-adjusted normalization of serum IGF-1

Cushing's Disease [1,9,12,13]

- Disease response indicated by reduction in urinary free cortisol (UFC), plasma adrenocorticotropic hormone (ACTH), late-night salivary cortisol (LNSC), and/or serum cortisol levels from baseline

V. Dosage/Administration [1]

Indication	Dose
Acromegaly	Initiate at 40 mg administered by intramuscular injection once every 4 weeks (28 days). – Titrate dosage based on treatment response and tolerability up to maximum 60 mg every 4 weeks for patients who have not normalized GH and/or IGF-1 levels after 3 months of treatment with the 40 mg dose.
Cushing's Disease	Initiate at 10 mg administered by intramuscular injection once every 4 weeks (28 days). – Titrate dosage based on treatment response and tolerability up to maximum 40 mg every 4 weeks for patients who have not normalized 24-hour urinary free cortisol (UFC) after 4 months of treatment with the 10 mg dose.

VI. Billing Code/Availability Information

HCPCS Code:

- J2502 - Injection, pasireotide long acting, 1 mg; 1 billable unit = 1 mg

NDC(s):

- Signifor LAR 10 mg single-use kit: 55292-0139-xx
- Signifor LAR 20 mg single-use kit: 55292-0140-xx
- Signifor LAR 30 mg single-use kit: 55292-0141-xx
- Signifor LAR 40 mg single-use kit: 55292-0142-xx
- Signifor LAR 60 mg single-use kit: 55292-0143-xx

VII. References

1. Signifor LAR [package insert]. Bridgewater, NJ; Recordati Rare Diseases, Inc.; July 2024. Accessed October 2025.

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Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
E22.0	Acromegaly and pituitary gigantism
E24.0	Pituitary-dependent Cushing's disease
E34.4	Constitutional tall stature

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC