

Federal Employee Program.

Blue Cross Blue Shield Association 750 9th St NW, Suite 900 Washington, D.C. 20001 1-800-624-5060 Fax 1-877-378-4727

5.30.038

Section: Prescription Drugs Effective Date: October 1, 2025

Subsection: Endocrine and Metabolic Drugs Original Policy Date: February 6, 2015

Subject: Signifor LAR Page: 1 of 4

Last Review Date: September 19, 2025

Signifor LAR

Description

Signifor LAR (pasireotide pamoate)

Background

Signifor LAR (pasireotide pamoate) is a once a month long-acting release intramuscular injection for the treatment of acromegaly in patients who are not surgical candidates or have had an inadequate response to surgery, and for patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative. Acromegaly is a rare and debilitating endocrine disorder caused by excess production of growth hormone (GH) and insulin-like growth factor-1 (IGF-1) levels. Cushing's disease is characterized by excess cortisol production. Signifor LAR exerts its pharmacological activity via binding to somatostatin receptors (SSTR). Pasireotide binds to SSTR2 and SSTR5 subtype receptors which may be relevant for inhibition of GH and corticotropin secretion (1).

Regulatory Status

FDA-approved indications: Signifor LAR is a somatostatin analog indicated for the treatment of: (1)

- 1. Patients with acromegaly who have had an inadequate response to surgery and/or for whom surgery is not an option
- 2. Patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative

Elevations in blood glucose levels have been seen in healthy volunteers and patients treated with Signifor LAR. The glycemic status [fasting plasma glucose (FPG) or hemoglobin A1c (HbA1c)] should be assessed prior to starting treatment with Signifor LAR (1).

Section:Prescription DrugsEffective Date:October 1, 2025Subsection:Endocrine and Metabolic DrugsOriginal Policy Date:February 6, 2015

Subject: Signifor LAR Page: 2 of 4

The safety and efficacy of Signifor LAR in pediatric patients have not been studied (1).

Related policies

Isturisa, Korlym, Mycapssa, Sandostatin LAR, Signifor, Somatuline Depot

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Signifor LAR may be considered **medically necessary** if the conditions indicated below are met.

Signifor LAR may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnoses

Patient must have **ONE** of the following:

- 1. Acromegaly
 - a. Surgery was not curative, or patient is not a candidate for surgery
 - b. Inadequate treatment response, intolerance, or contraindication to octreotide or lanreotide
- 2. Cushing's disease
 - Pituitary surgery was not curative, or patient is not a candidate for surgery

Prior – Approval Renewal Requirements

Age 18 years of age and older

Diagnoses

Section: Prescription Drugs Effective Date: October 1, 2025

Subsection: Endocrine and Metabolic Drugs Original Policy Date: February 6, 2015

Subject: Signifor LAR Page: 3 of 4

Patient must have **ONE** of the following:

1. Acromegaly

2. Cushing's disease

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 2 years

Prior - Approval Renewal Limits

Same as above

Rationale

Summary

Signifor LAR is a somatostatin analog indicated for the treatment of adult patients with acromegaly who have had an inadequate response to surgery and/or for whom surgery is not an option, and for patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative. Elevations in blood glucose levels have been seen in healthy volunteers and patients treated with Signifor LAR. The safety and efficacy of Signifor LAR in pediatric patients have not been studied (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Signifor LAR while maintaining optimal therapeutic outcomes.

References

1. Signifor LAR [package insert]. Lebanon, NJ: Recordati Rare Diseases Inc.; July 2024.

| Policy History | |
|----------------|--|
| Date | Action |
| January 2015 | Addition to PA |
| March 2015 | Annual editorial review and reference update |

5.30.038

Section:Prescription DrugsEffective Date:October 1, 2025Subsection:Endocrine and Metabolic DrugsOriginal Policy Date:February 6, 2015

Subject: Signifor LAR Page: 4 of 4

September 2015 Annual editorial review

December 2015 Annual review

Addition of inadequate treatment response, intolerance, or contraindication

to octreotide or lanreotide

September 2016 Annual review

Policy number change from 5.08.38 to 5.30.38

December 2017 Annual editorial review

July 2018 Addition of Cushing's disease indication

September 2018 Annual editorial review

December 2019 Annual editorial review and reference update. Changed approval duration

from lifetime to 2 years

September 2020 Annual review and reference update

December 2020 Annual review

September 2021 Annual review and reference update

June 2022 Annual review

December 2022 Annual review. Changed policy number to 5.30.038

September 2023 Annual review

September 2024 Annual review and reference update

September 2025 Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 19, 2025 and is effective on October 1, 2025.