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Section:	Prescription Drugs	**Effective Date:**	July 1, 2022
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	February 6, 2015
Subject:	Signifor LAR	**Page:**	1 of 4

Last Review Date: June 16, 2022

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 indication: 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).

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

Related policies
Bynfezia, 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** in patients 18 years and older with acromegaly or Cushing's disease and if the conditions indicated below are met.

Signifor LAR may be considered **investigational** in patients less than 18 years of age and 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
    a. 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

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.; June 2020.

Policy History

Date	Action
January 2015	Addition to PA
March 2015	Annual editorial review and reference update

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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 16, 2022 and is effective on July 1, 2022.