Pasireotide diaspartate (Signifor®) **Pasireotide pamoate (Signifor LAR®)**	**Place of Service** **Signifor® SC** **Home Infusion Administration** **Self Administration** **HCPCS: J3490** NDC: see section 5 **Signifor LAR®** **Office Administration** **Home Infusion Administration** **Outpatient Facility Infusion Administration** **Infusion Center Administration** **HCPCS: J2502** per 1 mg

Conditions listed in policy (*see criteria for details*)

- Acromegaly
- Cushing's disease

AHFS therapeutic class: somatostatin analog

Mechanism of action: pasireotide is a synthetic analog of somatostatin which binds to somatostatin receptors resulting in inhibition of ACTH secretion and a resultant decrease in cortisol secretion

(1) Special Instructions and Pertinent Information

Signifor SC is managed under the outpatient Pharmacy Benefit for self-administration. Please contact the member's Pharmacy Benefit for information on how to obtain this drug.

To submit a request to the Medical Benefit, please submit clinical information for prior authorization review and include medical rationale why the patient cannot self-administer this drug in the home.

For plans with self-injectables only covered under the Medical Benefit, please submit clinical information for prior authorization review.

Signifor LAR is managed under the Medical Benefit. Please submit clinical information for prior authorization review.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Signifor®/Signifor LAR® (pasitreotide) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Acromegaly

1. Being prescribed by an endocrinologist

Signifor LAR

Covered Doses
Up to 60 mg IM every 4 weeks

Coverage Period
Indefinite

ICD-10:
E22.0, E34.4

Cushing's disease

1. Patient cannot undergo pituitary surgery or pituitary surgery has not been curative

Signifor

Covered Doses
Up to 1.2 mg SC twice a day

Coverage Period
Indefinite

Signifor LAR

Covered Doses
Up to 40 mg IM every 4 weeks

Coverage Period
Indefinite

ICD-10:
E24.0, E24.3, E24.8, E24.9

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Signifor®/ Signifor LAR® (pasireotide) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:
Signifor SC – J3490
Single dose ampules in boxes of 60 ampules each, in the following strengths:
00078-0633-20 (0.3 mg/mL, #60 ampules, single-dose ampules)
00078-0633-06 (0.3 mg/mL, #6 ampules, single-dose ampules)

00078-0633-61 (0.3 mg/mL, #1 ampule, single-dose ampule)
00078-0634-20 (0.6 mg/mL, #60 ampules, single-dose ampules)
00078-0634-06 (0.6 mg/mL, #6 ampules, single-dose ampules)
00078-0634-61 (0.6 mg/mL, #1 ampule, single-dose ampule)
00078-0635-20 (0.9 mg/mL, #60 ampules, single-dose ampules)
00078-0635-06 (0.9 mg/mL, #6 ampules, single-dose ampules)
00078-0635-61 (0.9 mg/mL, #1 ampule, single-dose ampule)

Signifor LAR - J2502
10 mg, 20 mg, 30 mg, 40 mg, and 60 mg (single-use, powder in a vial to be reconstituted with the provided 2 mL diluent)
55292-139-01 (10 mg/2 mL)
55292-140-01 (20 mg/2 mL)
55292-141-01 (30 mg/2 mL)
55292-142-01 (40 mg/2 mL)
55292-143-01 (60 mg/2 mL)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Signifor ® (pasireotide) [Prescribing Information]. Lebanon, NJ: Recordati Rare Diseases Inc.; 1/2020.
- Signifor LAR® (pasireotide suspension) [Prescribing Information]. Lebanon, NJ. Recordati Rare Diseases Inc.; 7/2020.

(7) Policy Update

Date of last review: 3Q2021
Date of next review: 3Q2022
Changes from previous policy version:
- No clinical change to policy following routine annual review

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee