Medical Policy

Signifor® LAR (pasireotide)	
MEDICAL POLICY NUMBER	MED_Clin_Ops_092
CURRENT VERSION EFFECTIVE DATE	1/1/2024
APPLICABLE PRODUCT AND MARKET	Individual Family Plan: ALL Small Group: ALL Medicare Advantage: ALL

Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/Central Health Medicare Plan Medical Policy may contact the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.

If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at http://www.cms.gov for additional information.

Brand New Day/Central Health Medicare Plan medical policies address technology assessment of new and emerging treatments, devices, drugs, etc. They are developed to assist in administering plan benefits and do not constitute an offer of coverage nor medical advice. Brand New Day/Central Health Medicare Plan medical policies contain only a partial, general description of plan or program benefits and do not constitute a contract. Brand New Day/Central Health Medicare Plan does not provide health care services and, therefore, cannot guarantee any results or outcomes. Treating providers are solely responsible for medical advice and treatment of members. Our medical policies are updated based on changes in the evidence and healthcare coding and therefore are subject to change without notice. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). MCG™ and Care Guidelines® are trademarks of MCG Health, LLC (MCG).

PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity for Signifor® LAR (pasireotide) therapy.

POLICY

Prior Authorization and Medical Review is required.

Coverage for Signifor LAR will be provided for 12 months and may be renewed.

A. Patient is 18 years of age or older; **AND**

Medical Policy

Acromegaly

A. Signifor LAR is prescribed by, or in consultation with, an endocrinologist; **AND**
B. Patient has a diagnosis of acromegaly; **AND**
C. Patient has had an inadequate response to surgery OR surgery is not an option; **AND**
D. Patient has had an inadequate response, intolerance, or contraindication to Lanreotide depot injection (Somatuline Depot®) AND a dopamine agonist (e.g., bromocriptine, cabergoline).

Cushing's disease

A. Signifor LAR is prescribed by, or in consultation with, an endocrinologist; **AND**
B. Patient has a diagnosis of Cushing's disease; **AND**
C. Patient has had an inadequate response to surgery OR surgery is not an option.

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value

BACKGROUND

Signifor LAR is an injectable cyclohexapeptide somatostatin analog that exerts its pharmacological activity via binding to somatostatin receptors (SSTRs). There are five known human somatostatin receptor subtypes: SSTR 1, 2, 3, 4, and 5. These receptor subtypes are expressed in different tissues under normal physiological conditions. Somatostatin analogs bind to SSTRs with different potencies.

DEFINITIONS

1. SIGNIFOR LAR (pasireotide) for injectable suspension, for intramuscular use. Initial U.S. Approval: 2012
    a. SIGNIFOR LAR for injectable suspension is supplied in a single-use kit containing the following:
        i. One 6-mL brownish glass vial with a grey rubber stopper of SIGNIFOR LAR containing slightly yellow to yellow powder with a flip-off cap
        ii. One 3-mL glass barrel/grey rubber stopper prefilled syringe containing 2 mL of clear, colorless to slightly yellow/brown diluent solution for reconstitution
        iii. One sterile 20G x 1.5" stainless steel, polypropylene safety injection needle
        iv. One vial adapter made of polycarbonate for drug product reconstitution

CODING

Applicable NDC Codes	
00078-0642-81	SIGNIFOR LAR, pasireotide for injection (1) vial of 40 mg

55292-0142-01	SIGNIFOR LAR, pasireotide for injection (1) vial of 40 mg
00078-0641-81	SIGNIFOR LAR, pasireotide for injection (1) vial of 20 mg
55292-0140-01	SIGNIFOR LAR, pasireotide for injection (1) vial of 20 mg
55292-0141-01	SIGNIFOR LAR, pasireotide for injection (1) vial of 30 mg
55292-0143-01	SIGNIFOR LAR, pasireotide for injection (1) vial of 60 mg
00078-0748-81	SIGNIFOR LAR, pasireotide for injection (1) vial of 10 mg
55292-0139-01	SIGNIFOR LAR, pasireotide for injection (1) vial of 10 mg
00078-0741-81	SIGNIFOR LAR, pasireotide for injection (1) vial of 30 mg
00078-0643-81	SIGNIFOR LAR, pasireotide for injection (1) vial of 60 mg

Applicable Procedure Code	
J2502	Injection, pasireotide long acting, 1 mg

Applicable ICD-10 Codes	
E22.0	Acromegaly and pituitary gigantism
E24.0	Pituitary-dependent Cushing's disease

EVIDENCE BASED REFERENCES

1. Product Information: SIGNIFOR(R) LAR intramuscular injection suspension, pasireotide intramuscular injection suspension. Recordati Rare Diseases Inc (per FDA), Lebanon, NJ, 2020.

POLICY HISTORY

Original Effective Date	1/1/2022
Revised Date	November 8, 2022 – Annual Review and approval (no policy revisions made) March 1, 2023 - Adopted by MA UM Committee (no policy revisions made) January 1, 2024 - Updated to Brand New Day/Central Health Medicare Plan (no policy revisions made)
P&T Committee Endorsement	11/8/2022

Approved by Pharmacy and Therapeutics Committee on 11/8/2022