Signifor® LAR (pasireotide)

Humana

Pharmacy Coverage Policy

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Line of Business: Medicare, Commercial, Medicaid - Humana, Medicaid - Ohio
Policy Type: Prior Authorization

Disclaimer

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, take precedence over clinical policy and must be considered first in determining eligibility for coverage. Coverage may also differ for our Medicare and/or Medicaid members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including National Coverage Determinations (NCD), Local Medical Review Policies (LMRP) and/or Local Coverage Determinations. See the CMS website at http://www.cms.hhs.gov/. The member's health plan benefits in effect on the date services are rendered must be used. Clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically.

Description

Pasireotide pamoate is a long-acting cyclohexapeptide analog of natural somatostatin. The mechanism of action is believed to be similar to that of natural somatostatin which binds to somatostatin receptors on neuroendocrine tissue such as those found in growth hormone (GH) secreting pituitary adenomas. These tumors produce high levels of GH and insulin-like growth factor-1 (IGF-1) which are associated with acromegaly.

Signifor LAR is indicated for the treatment of patients with acromegaly and Cushing's disease who have had an inadequate response to surgery and/or for whom surgery is not an option.

Pasireotide pamoate for injectable suspension is available as Signifor LAR in 10mg, 20mg, 30mg, 40mg, and 60mg vials. The final concentration is 5mg/ml, 10mg/mL, 15mg/ml, 20mg/mL, and 30mg/mL, respectively, after reconstitution in 2mL of diluent.

Coverage Determination

Please note the following regarding medically accepted indications:

All reasonable efforts have been made to ensure consideration of medically accepted indications in this policy. Medically accepted indications are defined by CMS as those

uses of a covered Part D drug that are approved under the federal Food, Drug and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i) of the Act. These compendia guide review of off-label and off-evidence prescribing and are subject to minimum evidence standards for each compendium. Currently, this review includes the following references when applicable and may be subject to change per CMS:

- American Hospital Formulary Service-Drug Information (AHFS-DI)
- National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
- Truven Health Analytics Micromedex DrugDEX
- Elsevier/Gold Standard Clinical Pharmacology
- Wolters Kluwer Lexi-Drugs

Signifor LAR will require prior authorization. This agent may be considered medically necessary when the following criteria are met:

Cushing's Disease

- The member must have a diagnosis of Cushing's Disease; **AND**
- The member has had an inadequate response to pituitary surgery or pituitary surgery is not an option**; AND**
- The member does not have severe hepatic impairment (Child-Pugh C)

Acromegaly

- The member has a diagnosis of acromegaly; **AND**
- The member has had an inadequate response to pituitary surgery or pituitary surgery is not an option; **AND**
- The member has had previous treatment, contraindication, or intolerance with the somatostatin analogs, octreotide **OR** Somatuline Depot (lanreotide)*; **AND**

- No severe hepatic impairment (Child-Pugh C)

**For Medicare part B requests, the step therapy requirement does not apply if the request is a continuation of prior therapy within the past 365 days*

Signifor LAR (pasireotide) will be approved in plan year durations or as determined through clinical review.

Coverage Limitations

Signifor LAR (pasireotide) is not considered medically necessary for members with the following concomitant conditions:

- Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

Background

This is a prior authorization policy about Signifor LAR (pasireotide).

Acromegaly is an uncommonly diagnosed disorder with an annual estimated incidence of three to four cases per one million people. Acromegaly is a chronic disease resulting from excessive secretion of growth hormone (GH) and elevated levels of IGF-1. The usual cause of acromegaly is adenomas of the pituitary gland. Symptoms include headaches, profuse sweating, swelling, changes in facial features, joint disorders, and enlarged hands, feet and jaw. The goal of treatment is to reverse the effects of the excessive secretion of GH and normalize IGF-1 levels. Treatments include surgical removal of the adenoma, radiation therapy, and drug treatment, including dopamine agonists, GH receptor antagonists, and somatostatin analogues (i.e. octreotide and lanreotide).

Notes:

- Recommended tests prior to dosing: fasting plasma glucose, hemoglobin A1c, liver tests, electrocardiogram (ECG), and gallbladder ultrasound.
- After 3 months of initial treatment with 60mg every 28 days, the dose may be increased to a maximum of 60 mg for patients who have not normalized growth hormone (GH) and/or age and sex adjusted insulin-like growth factor-1 (IGF-1) levels and who tolerate this dose. In patients with moderate hepatic impairment (Child-Pugh B), the recommended initial dose is 20mg every 28 days up to a maximum dose of 40mg. Avoid use in patients with severe hepatic impairment (Child-Pugh C).
- Management of adverse reactions or over-response to treatment (age and sex adjusted IGF-1 less than the lower limit of normal) may require dose reduction. The dose may be decreased, either temporarily or permanently, by 20 mg decrements.
- Pasireotide is mainly eliminated by biliary excretion. Cholelithiasis has been frequently reported with pasireotide. Performing gallbladder ultrasounds before starting treatment and at 6-month intervals is recommended.

Cushing's Disease is an uncommon disorder with an estimated incidence of one to two cases per million. Cushing's Disease a chronic disease resulting from the excessive exposure to cortisol. The most common cause of Cushing's is a pituitary adenoma resulting in excessive release of ACTH and increased cortisol levels. Symptoms include "moon face", weight gain, hirsutism, and elevated blood glucose levels. The goal of treatment is to reverse the effects of excessive cortisol secretion and to normalize levels. Treatments include surgery, radiation therapy, and drug treatment including steroidogenesis inhibitors,pituitary targeted therapies, and glucocorticoid directed therapies.

Notes:

- Recommended tests prior to dosing: fasting plasma glucose, hemoglobin A1c, liver tests, electrocardiogram (ECG), and gallbladder ultrasound.
- After 4 months of treatment with the initial 10 mg dose every 28 days, the dose may be increased for patients who have not normalized 24-hour urinary free cortisol (UFC) up to 40 mg once every 28 days as tolerated. Avoid use in severe hepatic impairment (Child-Pugh C).
- Management of suspected adverse reactions or over response may require dose reduction to previously tolerated dose.

Provider Claims Codes

For medically billed requests, please visit www.humana.com/PAL. Select applicable Preauthorization and Notification List(s) for medical and procedural coding information.

Medical Terms

Signifor LAR; pasireotide; acromegaly; Cushing's Disease; intramuscular; pharmacy

References

1. Katznelson L, Atkinson JL, Cook DM, Ezzat SZ, Hamrahian AH, Miller KK, American Association of Clinical Endocrinologists. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of acromegaly--2011 update. *Endocr Pract*. 2011 Jul-Aug;17(Suppl 4):1-44.
2. Katznelson L, Laws ER Jr, Melmed S, et al; Endocrine Society. Acromegaly: an endocrine society clinical practice guideline. *J Clin Endocrinol Metab*. 2014;99(11):3933-3951.
3. Neiman LK, Biller BM, Findling JW, et al: Endocrine Society. Treatment of Cushing's Syndrome: An endocrine society clinical practice guideline. *J Clin Endocrin Metab*. 2015;100(8)2807-2831.
4. Signifor LAR [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; updated periodically.