Somatuline® Depot (lanreotide)

Humana

Pharmacy Coverage Policy

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

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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. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise without permission from Humana.

Description

Lanreotide is an octapeptide analog of natural somatostatin. The mechanism of action is believed to be similar to that of natural somatostatin.

Somatuline Depot (lanreotide) is indicated for:

- the long-term treatment of acromegalic patients who have had an inadequate response to or cannot be treated with surgery and/or radiotherapy
- the treatment of adult patients with unresectable, well- or moderately-differentiated, locally advanced or metastatic gastroenteropancreatic tumors (GEP-NETs) to improve progression-free survival
- the treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analogue rescue therapy

Lanreotide is available as Somatuline Depot Injection in 60mg/0.2mL, 90mg/0.3mL, and 120mg/0.5mL single-use prefilled syringes.

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

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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

Somatuline Depot (lanreotide) will require prior authorization. This agent may be considered medically necessary when the following criteria are met:

For generic lanreotide: Member has had prior therapy with or intolerance to brand Somatuline Depot* AND meets clinical criteria below.
**Previous treatment requirement does not apply to medical requests or Medicare Part B requests*

Acromegaly

- The member has a diagnosis of acromegaly; **AND**
- The member has had inadequate response to or cannot be treated with traditional therapies including surgery and/or radiation therapy

Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs)

- The member has a diagnosis of unresectable, well- or moderately-differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors

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Carcinoid Syndrome

- The member has a diagnosis of carcinoid syndrome with symptoms of flushing and/or diarrhea

Somatuline Depot (lanreotide) will be approved in plan year durations or as determined through clinical review.

Coverage Limitations

Somatuline Depot (lanreotide) is not considered medically necessary for members with the following concomitant condition(s):

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

Background

This is a prior authorization policy about Somatuline Depot (lanreotide acetate).

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).

Gastroenteropancreatic tumors are also classified as carcinoid tumors. The term *carcinoid* should be used for well-differentiated neuroendocrine tumors (NETs) or carcinomas of the GI tract only. Carcinoid tumors are rare, slow-growing tumors that originate in cells of the diffuse

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neuroendocrine system. They occur most frequently in tissues derived from the embryonic gut. Foregut tumors, which account for up to 25% of cases, arise in the lung, thymus, stomach, or proximal duodenum. Midgut tumors, which account for up to 50% of cases, arise in the small intestine, appendix, or proximal colon, with the appendix being the most common site of origin. Hindgut tumors, which account for approximately 15% of cases, arise in the distal colon or rectum. Other sites of origin include the gallbladder, kidney, liver, pancreas, ovary, and testis. Carcinoid syndrome occurs when carcinoid tumors secrete substances into the blood causing symptoms such as severe flushing and diarrhea.

Notes:

- Lanreotide may reduce gallbladder motility and lead to a gallstone formation therefore, patients may need to be monitored periodically. Discontinue if complications of cholthiasis are suspected.
- Patients treated with lanreotide may experience hypoglycemia or hyperglycemia. Blood glucose levels should be monitored when lanreotide treatment is initiated or when the dose is altered, and antidiabetic treatment should be adjusted accordingly.
- Decrease in heart rate may occur. Use with caution in at-risk patients.
- For carcinoid syndrome, patients should continue to use a short-acting somatostatin analog (i.e. octreotide) as rescue medication as needed for symptom control.

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

Somatuline Depot; lanreotide; acromegaly; gastroenteropancreatic neuroendocrine tumors

References

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