Lanreotide (Somatuline® Depot)

Prior Authorization Drug Coverage Policy

Effective Date: 9/1/2020
Revision Date: n/a
Review Date: 10/4/2021
Lines of Business: Commercial
Policy type: Prior Authorization

This Drug Coverage Policy provides parameters for the coverage of lanreotide (Somatuline® Depot). Consideration of medically necessary indications are based upon U.S. Food and Drug Administration (FDA) indications, recommended uses within the Centers of Medicare & Medicaid Services (CMS) five recognized compendia, including the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium (Category 1 or 2A recommendations), and peer-reviewed scientific literature eligible for coverage according to the CMS, Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 titled, "Off-Label Use of Anti-Cancer Drugs and Biologics." This policy evaluates whether the drug therapy is proven to be effective based on published evidence-based medicine.

Drug Description[1]

Lanreotide, the active component of Somatuline® Depot is an octapeptide analog of natural somatostatin. The mechanism of action of lanreotide is believed to be similar to that of natural somatostatin.

FDA Indications[1]

Lanreotide (Somatuline® Depot) is FDA indicated for the following:

- The treatment of adult patients with unresectable, well- or moderately-differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine 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 analog rescue therapy.

Coverage Determinations[1,2]

Lanreotide (Somatuline® Depot) will require prior authorization. This agent is considered medically necessary for the following oncology or oncology-related indications if all criteria below are met:

Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs)

- Treatment of adult patients with unresectable, well or moderately differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs)

Recommended dosage: 120 mg by deep subcutaneous injection every 4 weeks

Carcinoid Syndrome

- The member has a diagnosis of carcinoid syndrome

Recommended dosage: 120 mg by deep subcutaneous injection every 4 weeks

All indications:

- Lanreotide (Somatuline® Depot) will be approved through clinical review for up to a 12-month duration.

Coverage Limitations

Treatment with lanreotide (Somatuline® Depot) is not considered medically necessary for members with the following concomitant conditions:

- If the patient is already being treated with lanreotide (Somatuline® Depot) for GEP-NETs, an additional dose for the treatment of carcinoid syndrome should not be administered.
- The patient is being treated with long-acting octreotide.
- Indications not supported by NCCN category 2A or higher recommendations may not be considered medically necessary

Contraindications/Warnings/Precautions[1]

- Contraindications:
    - Hypersensitivity to lanreotide
- Warnings/Precautions:
    - Cholelithiasis and Complications of Cholelithiasis
    - Hyperglycemia and Hypoglycemia
    - Cardiovascular Abnormalities
    - Thyroid Function Abnormalities

For specific recommendations on contraindications, warnings and precautions, patient monitoring, and on dose adjustments and discontinuation, please refer to the current prescribing information.

Billing

- **Description**: Inj., lanreotide, 120 mg
    - HCPCS: J1930

Disclaimer

Drug Coverage Policies are developed as needed, regularly reviewed, updated at least annually, and are subject to change. Other policies and coverage determination guidelines may apply. Federal and state regulatory requirements and member specific benefit plan documents, if applicable, must be reviewed prior to this Drug Coverage Policy. This Drug Coverage Policy is for informational purposes only and does not constitute medical advice or dictate how providers should practice medicine. This policy should not be reproduced, stored in a retrieval system, or altered from its original form without written permission from Oncology Analytics, Inc.

References

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2. Lanreotide. NCCN Drugs & Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/#
3. Neuroendocrine and Adrenal Tumors (Version 1.2019). NCCN Clinical Practice Guidelines in Oncology. Available at: https://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf
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5. Ayyagari, R, Neary, M, Li, S Comparing the cost of treatment with octreotide long-acting release versus lanreotide in patients with metastatic gastrointestinal neuroendocrine tumors. Am Health Drug Benefits 2017; 10: 408–415.