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SOMATULINE DEPOT (lanreotide), LANREOTIDE

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Somatuline Depot/lanreotide is an injectable synthetic analogue of somatostatin, a hormone that regulates the endocrine and neurocrine system. Somatostatin inhibits many downstream hormones, such as those made in the gastrointestinal (GI) tract and pancreas, as well as growth hormone (GH). Because Somatuline Depot mimics somatostatin action, it can be used to treat acromegaly, a condition of excess GH and tumors of the neuroendocrine system (1-4).

Regulatory Status

FDA-approved indications: Somatuline Depot/lanreotide is a somatostatin analog indicated for long-term treatment of acromegalic patients who have had an inadequate response to or cannot be treated with surgery and/or radiotherapy and for 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 (1-2).

Somatuline Depot is also indicated for the treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analogue rescue therapy (1).

Off-Label Uses:

According to current oncology practice guidelines, Somatuline Depot/lanreotide may also be effective in treating the following neuroendocrine tumors (3-4):

- Adrenal gland tumors
- Tumors of the GI tract, lung, and thymus (carcinoid tumors)
- Tumors of the pancreas
- Poorly differentiated (high-grade)/large or small cell tumors

Safety and effectiveness of Somatuline Depot/lanreotide have not been established in pediatric patients (1-2).

Summary

Somatuline Depot/lanreotide is a somatostatin analogue that is used for the treatment of acromegaly due to its inhibition of growth hormone production. Somatuline Depot/lanreotide is also used for treatment of neuroendocrine tumors of the gastrointestinal, adrenal gland, thymus, lung,



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and pancreas, and poorly differentiated large or small cell NETs to decrease proliferation and prolong progression-free survival. Somatuline Depot is also approved for the treatment of carcinoid syndrome (1-4)

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Somatuline Depot/lanreotide while maintaining optimal therapeutic outcomes.

References

1. Somatuline Depot (lanreotide) [package insert]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; July 2024.
2. Lanreotide [package insert]. Warren, NJ: Cipla USA Inc; December 2021.
3. NCCN Clinical Practice Guidelines in Oncology® Neuroendocrine and Adrenal Tumors (Version 1.2024). National Comprehensive Cancer Network, Inc. June 2024. Accessed on July 24, 2024.
4. NCCN Drugs & Biologics Compendium® Lanreotide 2024. National Comprehensive Cancer Network, Inc. Accessed on July 24, 2024.