



## **RATIONALE FOR INCLUSION IN PA PROGRAM**

### **Background**

Sandostatin LAR (octreotide acetate) is a once a month, long-acting release intramuscular injection for the treatment of acromegaly, diarrhea or flushing episodes that are associated with metastatic carcinoid tumors, and diarrhea that is associated with vasoactive intestinal peptide (VIP)-secreting tumors. Acromegaly is a rare and debilitating endocrine disorder caused by excess production of growth hormone (GH) and insulin-like growth factor-1 (IGF-1). Metastatic carcinoid tumors are found along the gastrointestinal (GI) tract and release too much serotonin into the body, while VIP-secreting tumors cause increased secretions from the intestines. Sandostatin LAR mimics natural somatostatin by inhibiting the secretion of growth hormone, glucagon, insulin, serotonin, gastrin, VIP, secretin, motilin, and pancreatic polypeptide (1).

### **Regulatory Status**

FDA-approved indications: Sandostatin LAR is a somatostatin analogue indicated for the treatment of patients who have responded to and tolerated Sandostatin subcutaneous injections for (1):

1. Long-term maintenance therapy in acromegalic patients who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option
2. Severe diarrhea/flushing episodes associated with metastatic carcinoid tumors
3. Profuse watery diarrhea associated with VIP-secreting tumors

### Limitations of Use: (1)

In patients with carcinoid syndrome and VIPomas, the effect of Sandostatin subcutaneous injection and Sandostatin LAR on tumor size, rate of growth, and development of metastases has not been determined.

### Off-Label Uses: (2)

The National Comprehensive Cancer Network (NCCN) includes these additional indications:

1. In the treatment of patients with neuroendocrine tumors (NETs) of the gastrointestinal tract and/or pancreas with carcinoid syndrome.
2. In the treatment of patients with neuroendocrine tumors (NETs) of the gastrointestinal tract and/or pancreas for management of locoregional unresectable disease and/or distant metastases.



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## **SANDOSTATIN LAR (octreotide acetate)**

Safety and effectiveness of Sandostatin LAR in pediatric patients have not been established (1).

### **Summary**

Sandostatin LAR is a somatostatin analog indicated for the treatment of adults with acromegaly, diarrhea or flushing episodes associated with metastatic carcinoid tumors, or diarrhea associated with VIP-secreting tumors. Prior to initiation, patients must show a response to and tolerate Sandostatin subcutaneous injections for at least two weeks. Safety and effectiveness of Sandostatin LAR in pediatric patients have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Sandostatin LAR while maintaining optimal therapeutic outcomes.

### **References**

1. Sandostatin LAR [package insert]. East Hanover, NJ: Novartis Pharmaceuticals. Pharmaceuticals Corporation; July 2023.
2. NCCN Drugs & Biologics Compendium® Octreotide acetate 2024. National Comprehensive Cancer Network, Inc. Accessed on July 18, 2024.