Sandostatin LAR

Description

Sandostatin LAR (octreotide acetate)

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 indication: 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
Limitation 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.

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

Related policies
Signifor LAR, Somatuline Depot

Policy
This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Sandostatin LAR may be considered medically necessary in patients 18 years and older with acromegaly; patients with severe diarrhea or flushing episodes associated with metastatic carcinoid tumors; severe diarrhea associated with VIP-secreting tumors; or neuroendocrine tumor of the gastrointestinal tract or pancreas (GEP-NETs); and if the conditions indicated below are met.

Sandostatin LAR is considered investigational in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age  18 years of age and older

Diagnoses
Patient must have **ONE** of the following:

1. **Acromegaly**
   a. Inadequate response or patient is **NOT** a candidate for **ALL** of the following:
      i. Surgery resection
      ii. Pituitary irradiation
      iii. Bromocriptine mesylate
   b. Response to and tolerance of prior treatment with 2 weeks of immediate release octreotide

2. **Severe diarrhea or flushing episodes associated with metastatic carcinoid tumor(s)**
   a. Response to and tolerance of prior treatment with 2 weeks of immediate release octreotide
   b. Prescriber agrees to simultaneously administer Sandostatin LAR and immediate release octreotide injections for at least two weeks when initiating therapy

3. **Profuse watery diarrhea associated with VIP-secreting tumor(s)**
   a. Response to and tolerance of prior treatment with 2 weeks of immediate release octreotide
   b. Prescriber agrees to simultaneously administer Sandostatin LAR and immediate release octreotide injections for at least two weeks when initiating therapy

4. **Neuroendocrine Tumor of the Gastrointestinal Tract or Pancreas (GEP-NETs)**

**Prior – Approval Renewal Requirements**

**Age**

18 years of age or older

**Diagnoses**

Patient must have **ONE** of the following:

1. **Acromegaly**
2. **Severe diarrhea or flushing episodes associated with metastatic carcinoid tumor(s)**
3. **Profuse watery diarrhea associated with VIP-secreting tumor(s)**
4. **Neuroendocrine Tumor of the Gastrointestinal Tract or Pancreas (GEP-NETs)**
AND the following:
   a. NO disease progression or unacceptable toxicity

**Policy Guidelines**

**Pre - PA Allowance**

None

**Prior - Approval Limits**

**Duration**

12 months

**Prior – Approval *Renewal* Limits**

Same as above

**Rationale**

**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**


**Policy History**

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<td>September 2016</td>
<td>Addition to PA</td>
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<td>December 2016</td>
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<td>December 2017</td>
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### Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective on January 1, 2020.