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.

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 in patients with an Inadequate response or patient is NOT a candidate for all of the following: surgery resection, pituitary irradiation or bromocriptine mesylate; patients with severe diarrhea or flushing episodes associated with metastatic carcinoid tumors and the prescriber agrees to simultaneously administer Sandostatin LAR and immediate release octreotide injections for at least two weeks when initiating therapy; severe diarrhea associated with VIP-secreting tumors and the prescriber agrees to simultaneously administer Sandostatin LAR and immediate release octreotide injections for at least two weeks when initiating therapy; patients who have responded to and tolerated Sandostatin subcutaneous injection.

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

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

   AND the following:
   1. Response to and tolerance of prior treatment with 2 weeks of immediate release octreotide

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)

   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

Duration 12 months

Rationale

Summary
Sandostatin LAR is a somatostatin analog indicated for the treatment of adult 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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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 15, 2017 and is effective on October 1, 2017.