Medical Necessity Guidelines:
Somatostatin Analogs for Non-Oncology Indications

Effective: January.1.2023

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	Yes ☒ No ☐

Applies to:

☒ CarePartners of Connecticut Medicare Advantage HMO plans, Fax 617-673-0956
☒ CarePartners of Connecticut Medicare Advantage PPO plans, Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration (FDA) Approved Indications for Non-oncology Uses

Sandostatin® (octreotide) is a somatostatin analog indicated for:

- **Acromegaly**
  To reduce blood levels of growth hormone (GH) and insulin like growth factor (IGF-I) in acromegaly patients who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses
- **Carcinoid Tumors**
  For the symptomatic treatment of patients with metastatic carcinoid tumors where it suppresses or inhibits the severe diarrhea and flushing episodes associated with the disease
- **Vasoactive Intestinal Peptide (VIP)-Secreting Tumors**
  For the treatment of the profuse watery diarrhea associated with VIP-secreting tumors (aka VIPomas)

Sandostatin® LAR (octreotide) is a somatostatin analog indicated for:

- **Acromegaly**
  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. The goal of treatment in acromegaly is to reduce growth hormone and IGF-1 levels to normal
- **Carcinoid Tumors**
  Long-term treatment of the severe diarrhea and flushing episodes associated with metastatic carcinoid tumors
- **Vasoactive Intestinal Peptide (VIP)-Secreting Tumors**
  For the long-term treatment of the profuse watery diarrhea associated with VIP-secreting tumors (aka VIPomas)

Signifor LAR (pasireotide) is a somatostatin analog indicated for the treatment of:

- **Acromegaly**
  Patients with acromegaly who have had an inadequate response to surgery and/ or for whom surgery is not an option.
- **Cushing's Disease**
  Patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative.

Somatuline® Depot (lanreotide**)** is a somatostatin analog indicated for:

- **Acromegaly**

For the long-term treatment of acromegalic patients who have had an inadequate response to or cannot be treated with surgery and/or radiotherapy.

- **Gastroenteropancreatic Neuroendocrine Tumors**

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.

- **Carcinoid Syndrome**

For the treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analog rescue therapy.

Clinical Guideline Coverage Criteria

The Plan may cover Sandostatin (octreotide) (for office administration), Sandostatin® LAR (octreotide for injectable suspension), Signifor® LAR (pasireotide for injectable suspension) and Somatuline® Depot (lanreotide injection) when all the following clinical criteria is met:

Acromegaly

The plan may authorize coverage of octreotide (generic Sandostatin), Sandostatin LAR (octreotide), Signifor LAR (pasireotide) or Somatuline Depot (lanreotide) for Members when **all** of the following criteria are met:

1. Documented diagnosis of acromegaly

AND

2. The requested drug has been prescribed by an endocrinologist or recommended in consult with an endocrinologist

AND

3. There is documentation that the Member is not a candidate for surgery and/or radiation, or has had an inadequate response to surgery and/or radiation

Cushing's Disease

The plan may authorize coverage of Signifor LAR (pasireotide) for Members when all of the following criteria are met:

1. Documented diagnosis of Cushing's Disease

AND

2. The requested drug has been prescribed by an endocrinologist or recommended in consult with an endocrinologist

AND

3. There is documentation that the Member is not a candidate for pituitary surgery, or that pituitary surgery has not been curative.

Limitations

- None

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J2353	Injection, octreotide, depot form for intramuscular injection, 1 mg
J2354	Injection, octreotide, non-depot form for subcutaneous or intravenous injection, 25 mcg
J2502	Injection, pasireotide long acting, 1 mg
J1932	Injection, lanreotide, (cipla), 1 mg

References:

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2. Colao A, Bronstein MD, Freda P, et al. Pasireotide versus octreotide in acromegaly: a head-to-head superiority study. *J Clin Endocrinol Metab*. 2014 Mar;99(3):791-9.
3. Katznelson L, Atkinson JL, Cook DM et al. American Association of Clinical Endocrinologists. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of acromegaly--2011 update. *Endocr Pract*. 2011 Jul-Aug; 17 Suppl 4:1- 44.
4. Mathioudakis N, Salvatori R. Management options for persistent postoperative acromegaly. *Neurosurg Clin N Am*. 2012 Oct; 23(4):621-38.

5. Melmed S, Casanueva FF, Cavagnini F, et al. Guidelines for acromegaly management. *J Clin Endocrinol Metab.* 2002; 87:4054–4058.
6. Melmed S, Colao A, Barkan A, et al. Guidelines for acromegaly management: an update. *J Clin Endocrinol Metab*. 2009; 94:1509–1517.
7. Octreotide injection [prescribing information]. East Brunswick, NJ: Heritage Pharmaceuticals, Inc. May 2019.
8. Sandostatin LAR (octreotide acetate for injectable suspension) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2021.
9. Signifor LAR (pasireotide) [package insert]. Lebanon, NJ. Recordati Rare Diseases; June 2020.
10. Somatuline Depot (lanreotide) [package insert]. Cambridge, MA. Ipsen Biopharmaceuticals. June 2019.
11. Shlomo, M. Acromegaly. N Engl J Med. December 14, 2006; Vol. 355 (24): 2558-2573.
12. The National Endocrine and Metabolic Diseases Information Service. NIH Publication No. 07–3924, April 2007: endocrine.niddk.nih.gov/pubs/acro/acro.htm.
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Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T).

September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC).

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.