Reference number(s)
2748-A

STANDARD MEDICARE PART B MANAGEMENT

SANDOSTATIN LAR (octreotide acetate for injectable suspension)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
Sandostatin LAR Depot is indicated in patients in whom initial treatment with Sandostatin injection has been shown to be effective and tolerated.
1. Indicated for 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. Indicated for long-term treatment of the severe diarrhea and flushing episodes associated with metastatic carcinoid tumors.
3. Indicated for long-term treatment of the profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors.

B. Compendial Uses
1. Neuroendocrine tumors (NETs)
   a. NETs of the gastrointestinal (GI) tract, lung, and thymus (carcinoid tumors) or unresected primary gastrinoma
   b. NETs of the pancreas
2. Pheochromocytoma/paraganglioma
3. Meningiomas
4. Thymomas and thymic carcinomas
5. Treatment of diarrhea in acquired immunodeficiency syndrome (AIDS)
6. Bowel obstruction due to peritoneal carcinomatosis
7. Postgastrectomy dumping syndrome
8. Pediatric hypothalamic obesity
9. Hepatocellular carcinoma
10. Pancreatic pleural effusion
11. Pituitary adenoma
12. Graves' ophthalmopathy
13. von Willebrand disorder

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:
For acromegaly:

1. For initial approval: Laboratory report indicating high pretreatment insulin-like growth factor-1 (IGF-1) level and chart notes indicating an inadequate or partial response to surgery or radiotherapy or a clinical reason for not having surgery or radiotherapy.
2. For continuation: Laboratory report indicating normal current IGF-1 levels or chart notes indicating that the member's IGF-1 level has decreased or normalized since initiation of therapy

III. CRITERIA FOR INITIAL APPROVAL

A. Acromegaly

Authorization of 12 months may be granted for the treatment of acromegaly when all of the following criteria are met:

1. Member has a high pretreatment insulin-like growth factor-1 (IGF-1) level for age and/or gender based on the laboratory reference range.
2. Member had an inadequate or partial response to surgery or radiotherapy OR there is a clinical reason why the member has not had surgery or radiotherapy.

B. Carcinoid syndrome

Authorization of 12 months may be granted for treatment of carcinoid syndrome.

C. Vasoactive intestinal peptide tumors (VIPomas)

Authorization of 12 months may be granted for management of symptoms related to hormone hypersecretion of VIPomas.

D. Neuroendocrine tumors (NETs)

1. Authorization of 12 months may be granted for treatment of NETs of the gastrointestinal (GI) tract, lung, thymus (carcinoid tumors) or unresected primary gastrinoma.
2. Authorization of 12 months may be granted for treatment of NETs of the pancreas.

E. Pheochromocytoma and paraganglioma

Authorization of 12 months may be granted for treatment of pheochromocytoma/paraganglioma.

F. Meningiomas

Authorization of 12 months may be granted to members for treatment of unresectable meningioma.

G. Thymomas and thymic carcinomas

Authorization of 12 months may be granted for treatment of thymoma and thymic carcinoma.

H. Bowel obstruction due to peritoneal carcinomatosis

Authorization of 12 months may be granted for treatment of bowel obstruction due to peritoneal carcinomatosis.

I. Postgastrectomy dumping syndrome

Authorization of 12 months may be granted for treatment of postgastrectomy dumping syndrome.

J. Hepatocellular carcinoma

Authorization of 12 months may be granted for treatment of hepatocellular carcinoma.

K. Pituitary adenoma

Authorization of 12 months may be granted for treatment of pituitary adenoma.

L. Diarrhea in acquired immunodeficiency syndrome (AIDS)

Authorization of 12 months may be granted for treatment of diarrhea in a member with acquired immunodeficiency syndrome (AIDS).

M. Pediatric hypothalamic obesity
Authorization of 12 months may be granted for treatment of hypothalamic obesity in a pediatric member.

N. Pancreatic pleural effusion
Authorization of 12 months may be granted for treatment of pancreatic pleural effusion.

O. Graves' ophthalmopathy
Authorization of 12 months may be granted for treatment of Graves' ophthalmopathy.

P. von Willebrand disorder
Authorization of 12 months may be granted for treatment of von Willebrand disorder.

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:
1. The member is currently receiving therapy with Sandostatin LAR.
2. Sandostatin LAR is being used to treat an indication enumerated in Section II.
3. The member is receiving benefit from therapy.

V. REFERENCES

1. Sandostatin LAR Depot [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2019.
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3. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed November 13, 2020.
4. The NCCN Clinical Practice Guidelines in Oncology® Neuroendocrine and Adrenal Tumors (Version 1.2019). © 2020 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed November 13, 2020.
5. The NCCN Clinical Practice Guidelines in Oncology® Thymomas and Thymic Carcinomas. (Version 1.2020). © 2020 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed November 13, 2020.
6. The NCCN Clinical Practice Guidelines in Oncology® Central Nervous System Cancers (Version 3.2019). © 2020 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed November 13, 2020.
7. Katznelson L, Laws ER, Melmed S, et al. Acromegaly: an endocrine society clinical practice guideline. *J Clin Endocrinol Metab*. 2014;99:3933-3951.
8. American Association of Clinical Endocrinologists Acromegaly Guidelines Task Force. Medical guidelines for clinical practice for the diagnosis and treatment of acromegaly – 2011 update. *Endocr Pract*. 2011;17(suppl 4):1-44.