Reference number
1734-A

SPECIALTY GUIDELINE MANAGEMENT

SANDOSTATIN (octreotide acetate injection)
SANDOSTATIN LAR DEPOT (octreotide acetate for injectable suspension)
octreotide acetate injection

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
1. octreotide acetate/Sandostatin:
   a. Indicated to reduce blood levels of growth hormone and IGF-1 (somatomedin C) 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.
   b. Indicated 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.
   c. Indicated for the treatment of the profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors.

2. Sandostatin LAR: Sandostatin LAR Depot is indicated in patients in whom initial treatment with Sandostatin injection has been shown to be effective and tolerated.
   a. 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.
   b. Indicated for long-term treatment of the severe diarrhea and flushing episodes associated with metastatic carcinoid tumors.
   c. 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. Adrenal gland tumors
   b. Tumors of the gastrointestinal (GI) tract, lung, and thymus (carcinoid tumors)
   c. Tumors of the pancreas
2. Meningiomas
3. Thymomas and thymic carcinomas
4. Congenital hyperinsulinism (CHI)/persistent hyperinsulinemic hypoglycemia of infancy (PHHI) (octreotide and Sandostatin only)

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Acromegaly
Authorization of 24 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. Neuroendocrine tumors (NETs)/carcinoid syndrome

1. Tumors of the gastrointestinal (GI) tract (carcinoid tumor)
   Authorization of 24 months may be granted for treatment of metastatic or unresectable NETs of the GI tract.
2. Tumors of the thymus (carcinoid tumor)
   Authorization of 24 months may be granted for treatment of metastatic or unresectable NETs of the thymus.
3. Tumors of the lung (carcinoid tumor)
   Authorization of 24 months may be granted for treatment of metastatic or unresectable NETs of the lung.
4. Tumors of the pancreas
   Authorization of 24 months may be granted for treatment of NETs of the pancreas.
5. Tumors of the adrenal gland
   Authorization of 24 months may be granted for treatment of NETs of the adrenal gland.

C. Meningiomas

Authorization of 24 months may be granted to members for treatment of unresectable meningioma.

D. Thymomas and thymic carcinomas

Authorization of 24 months may be granted for treatment of thymomas and thymic carcinomas.

E. Congenital hyperinsulinism (CHI)/persistent hyperinsulinemic hypoglycemia of infancy (octreotide and Sandostatin only)

Authorization of 6 months may be granted for treatment of CHI and persistent hyperinsulinemic hypoglycemia in an infant.

III. CONTINUATION OF THERAPY

A. Acromegaly

Authorization of 24 months may be granted for continuation of therapy for acromegaly when the member's IGF-1 level has decreased or normalized since initiation of therapy.

B. All other indications

Members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Octreotide acetate [package insert]. Rockford, IL: Mylan Institutional LLC; May 2015.
2. Sandostatin [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2012.
3. Sandostatin LAR Depot [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2016.
4. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org. Accessed February 8, 2018.
5. Katznelson L, Laws ER, Melmed S, et al. Acromegaly: an endocrine society clinical practice guideline. *J Clin Endocrinol Metab*. 2014;99:3933-3951.

6. 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.
7. The NCCN Clinical Practice Guidelines in Oncology® Neuroendocrine Tumors (Version 3.2017). © 2017 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed February 8, 2018.
8. Rinke A, Muller H, Schade-Brittinger C, et al. Placebo-controlled, double-blind, prospective, randomized study on the effect of octreotide LAR in the control of tumor growth in patients with metastatic neuroendocrine midgut tumors: a report from the PROMID study group. *J Clin Oncol*. 2009;27:4656-4663.
9. The NCCN Clinical Practice Guidelines in Oncology® Central Nervous System Cancers (Version 1.2017). © 2017 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed February 8, 2018.
10. The NCCN Clinical Practice Guidelines in Oncology® Thymomas and Thymic Carcinomas. (Version 1.2018). © 2018 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed February 8, 2018.