

Medical Policy: Sandostatin LAR (octreotide suspension)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.103	January 8, 2024	October 12, 2020

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

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Length of Authorization

Coverage will be provided for 6 months and may be renewed.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time) [Medical Benefit]:

- Acromegaly: 40 units every 28 days
- Carcinoid Tumors and VIPomas: 30 units every 28 days
- Thymic Carcinoma/Thymoma: 20 units every 14 days

Guideline

I.Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient is at least 18 years old; **AND**
 - 1. **Carcinoid tumors/Neuroendocrine tumors (e.g. GI tract, Lung, Thymus, Pancreas, Adrenal) †**
 - A. Patient has severe diarrhea/flushing episodes (carcinoid syndrome) †; **OR**
 - B. Primary treatment of unresected primary gastrinoma; **OR**
 - C. Used for management of primary non-metastatic glucagonoma; **OR**
 - D. Used for the management of locoregional advanced or metastatic disease of the bronchopulmonary, thymic, gastrointestinal tract; **OR**
 - E. Used for treatment of neuroendocrine tumor of the pancreas; **OR**
 - F. Used for symptom control for Pheochromocytoma/Paraganglioma.
 - 2. **Diarrhea associated with Vasoactive intestinal peptide tumors (VIPomas) †**
 - A. Patient has profuse watery diarrhea
 - 3. **Acromegaly †**
 - A. Patient diagnosis confirmed by elevated (age-adjusted) or equivocal serum IGF-1 as well as inadequate suppression of GH after a glucose load; **AND**
 - B. Used as long-term maintenance therapy; **AND**
 - C. Patient's tumor has been visualized on imaging studies (i.e., MRI or CT-scan); **AND**
 - D. Baseline growth hormone (GH) and IGF-I blood levels (renewal will require reporting of current levels); **AND**
 - i. Patient has documented inadequate response to surgery and/or radiotherapy; **OR**
 - ii. Surgery and/or radiotherapy is not an option for this patient.
 - 4. **Meningiomas (CNS Cancers) ‡**
 - A. Patient's disease is unresectable; **AND**
 - B. Patient's disease is recurrent or progressive meningioma; **AND**
 - C. Radiation treatment is not possible for the patient's disease
 - 5. **Thymic Carcinomas/Thymomas ‡**
 - A. Must be used as second-line therapy with or without prednisone
 - i. Patient has unresectable disease following first-line chemotherapy for potentially resectable locally advanced disease, solitary metastasis, or ipsilateral pleural metastasis; **OR**
 - ii. Patient has extrathoracic metastatic disease
- † FDA Approved Indication(s); ‡ Compendia recommended indication(s)

II. Renewal Criteria

1. Patient continues to meet criteria identified above; **AND**
2. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: biliary tract abnormalities, hypothyroidism, goiter, sinus bradycardia, cardiac arrhythmias, cardiac conduction abnormalities, pancreatitis, etc.; **AND**
 - a. Disease response with improvement in patient's symptoms including reduction in symptomatic episodes (such as diarrhea, rapid gastric dumping, flushing, bleeding, etc.) and/or stabilization of glucose levels and/or decrease in size of tumor or tumor spread; **OR**
 - b. **Acromegaly ONLY:**
 - i. Disease response indicated by reduction of growth hormone (GH) and/or IGF-I blood levels from baseline; **OR**

- ii. Age-adjusted normalization of serum IGF-1; **OR**
- c. **Neuroendocrine tumors (gastrointestinal tract, bronchopulmonary, thymus, or pancreas) ONLY:**
Patient has had disease progression and therapy will be continued in patients with functional tumors.

Limitations/Exclusions

Sandostatin is not considered medically necessary for indications other than those listed above due to insufficient evidence of therapeutic value.

Applicable Procedure Codes

Code	Description
J2353	Injection, octreotide, depot form for intramuscular injection, 1 mg: 1 mg = 1 billable unit

Applicable NDCs

Code	Description
00078-0811-XX	10 mg single-use kit
00078-0818-XX	20 mg single-use kit
00078-0825-XX	30 mg single-use kit

ICD-10 Diagnoses

Code	Description
C25.4	Malignant neoplasm of endocrine pancreas
C37	Malignant neoplasm of thymus
C70.0	Malignant neoplasm of cerebral meninges
C70.1	Malignant neoplasm of spinal meninges
C70.9	Malignant neoplasm of meninges, unspecified
C7A.00	Malignant carcinoid tumor of unspecified site
C7A.010	Malignant carcinoid tumor of the duodenum
C7A.011	Malignant carcinoid tumor of the jejunum
C7A.012	Malignant carcinoid tumor of the ileum
C7A.019	Malignant carcinoid tumor of the small intestine, unspecified portion
C7A.020	Malignant carcinoid tumor of the appendix
C7A.021	Malignant carcinoid tumor of the cecum
C7A.022	Malignant carcinoid tumor of the ascending colon
C7A.023	Malignant carcinoid tumor of the transverse colon
C7A.024	Malignant carcinoid tumor of the descending colon
C7A.025	Malignant carcinoid tumor of the sigmoid colon
C7A.026	Malignant carcinoid tumor of the rectum
C7A.029	Malignant carcinoid tumor of the large intestine, unspecified portion
C7A.090	Malignant carcinoid tumor of the bronchus and lung
C7A.091	Malignant carcinoid tumor of the thymus
C7A.092	Malignant carcinoid tumor of the stomach
C7A.093	Malignant carcinoid tumor of the kidney

C7A.094	Malignant carcinoid tumor of the foregut, unspecified
C7A.095	Malignant carcinoid tumor of the midgut, unspecified
C7A.096	Malignant carcinoid tumor of the hindgut, unspecified
C7A.098	Malignant carcinoid tumors of other sites
C7A.1	Malignant poorly differentiated neuroendocrine tumors
C7A.8	Other malignant neuroendocrine tumors
C7B.00	Secondary carcinoid tumors, unspecified site
C7B.01	Secondary carcinoid tumors of distant lymph nodes
C7B.02	Secondary carcinoid tumors of liver
C7B.03	Secondary carcinoid tumors of bone
C7B.04	Secondary carcinoid tumors of peritoneum
C7B.09	Secondary carcinoid tumors of other sites
C7B.8	Other secondary neuroendocrine tumors
C74.10	Malignant neoplasm of medulla of unspecified adrenal gland
C74.11	Malignant neoplasm of medulla of right adrenal gland
C74.12	Malignant neoplasm of medulla of left adrenal gland
C74.90	Malignant neoplasm of unspecified part of unspecified adrenal gland
C74.91	Malignant neoplasm of unspecified part of right adrenal gland
C74.92	Malignant neoplasm of unspecified part of left adrenal gland
C75.5	Malignant neoplasm of aortic body and other paraganglia
D15.0	Benign neoplasm of thymus
D32.0	Benign neoplasm of cerebral meninges
D32.1	Benign neoplasm of spinal meninges
D32.9	Benign neoplasm of meninges, unspecified
D3A.00	Benign carcinoid tumor of unspecified site
D3A.010	Benign carcinoid tumor of the duodenum
D3A.011	Benign carcinoid tumor of the jejunum
D3A.012	Benign carcinoid tumor of the ileum
D3A.019	Benign carcinoid tumor of the small intestine, unspecified portion
D3A.020	Benign carcinoid tumor of the appendix
D3A.021	Benign carcinoid tumor of the cecum
D3A.022	Benign carcinoid tumor of the ascending colon
D3A.023	Benign carcinoid tumor of the transverse colon
D3A.024	Benign carcinoid tumor of the descending colon
D3A.025	Benign carcinoid tumor of the sigmoid tumor
D3A.026	Benign carcinoid tumor of the rectum
D3A.029	Benign carcinoid tumor of the large intestine, unspecified portion
D3A.090	Benign carcinoid tumor of the bronchus and lung
D3A.091	Benign carcinoid tumor of the thymus
D3A.092	Benign carcinoid tumor of the stomach
D3A.0963A	Benign carcinoid tumor of the hindgut, unspecified
D3A.098	Benign carcinoid tumors of other sites
D42.0	Neoplasm of uncertain behavior of cerebral meninges
D42.1	Neoplasm of uncertain behavior of spinal meninges
D42.9	Neoplasm of uncertain behavior of meninges, unspecified
E16.1	Other hypoglycemia

E16.3	Increased secretion of glucagon
E16.4	Increased secretion of gastrin
E16.8	Other specified disorders of pancreatic internal secretion
E22.0	Acromegaly and pituitary gigantism
E34.0	Carcinoid syndrome
Z85.020	Personal history of malignant carcinoid tumor of stomach
Z85.030	Personal history of malignant carcinoid tumor of large intestine
Z85.040	Personal history of malignant carcinoid tumor of rectum
Z85.060	Personal history of malignant carcinoid tumor of small intestine
Z85.07	Personal history of malignant neoplasm of pancreas
Z85.110	Personal history of malignant carcinoid tumor of bronchus and lung
Z85.230	Personal history of malignant carcinoid tumor of thymus
Z85.841	Personal history of malignant neoplasm of brain
Z85.848	Personal history of malignant neoplasm of other parts of nervous system
Z85.858	Personal history of malignant neoplasm of other endocrine glands

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	1/8/2024	Annual Review: Updated dosing limits; Initial Criteria: Acromegaly: Added: "Patient diagnosis confirmed by elevated (age-adjusted) or equivocal serum IGF-1 as well as inadequate suppression of GH after a glucose load; AND Used as long-term maintenance therapy; AND Patient's tumor has been visualized on imaging studies (i.e., MRI or CT-scan); AND" Thymic Carcinomas/Thymomas Added: "Patient has unresectable disease following first-line chemotherapy for potentially resectable locally advanced disease, solitary metastasis, or ipsilateral pleural metastasis; OR Patient has extrathoracic metastatic disease" Renewal Criteria Acromegaly : added: "Age-adjusted normalization of serum IGF-1" added renewal criteria for neuroendocrine tumors
EmblemHealth & ConnectiCare	5/09/2023	Annual Review: updated formatting, no criteria changes
EmblemHealth & ConnectiCare	1/12/2023	Transfer to New Template
EmblemHealth & ConnectiCare	10/12/2020	Clarified use in carcinoid tumors/neuroendocrine tumors; added use in Pheochromocytoma/Paraganglioma; removed separate criteria for pancreatic cancer renewal

References

1. Sandostatin LAR [package insert]. East Hanover, NJ; Novartis Pharmaceuticals Corporation; April 2019. Accessed October 2020.
2. Giustina A, Chanson P, Kleinberg D, et al. Expert consensus document: A consensus on the medical treatment of acromegaly. Nat Rev Endocrinol. 2014 Apr; 10(4):243-8. doi: 10.1038/nrendo.2014.21. Epub 2014 Feb 25.

3. Katznelson L, Laws ER Jr, Melmed S, et al. Acromegaly: an endocrine society clinical practice guideline. *J Clin Endocrinol Metab.* 2014 Nov; 99(11):3933-51. doi: 10.1210/jc.2014-2700. Epub 2014 Oct 30.
4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Octreotide. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2018.
5. Palmetto GBA. Local Coverage Determination (LCD): Octreotide Acetate for Injectable Suspension (Sandostatin LAR depot) (L33438). Centers for Medicare & Medicaid Services, Inc. Updated on 12/7/2017 with effective date 2/26/2018. Accessed March 2018.