# Medical Policy:
## Sandostatin LAR (octreotide suspension)

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



## 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 asinadequate 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 |

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| 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 |

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| 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:<br>Added: "Patient diagnosis confirmed by elevated (age-adjusted) or equivocal serum IGF-1 as well asinadequate suppression of GH after a glucose load; AND<br>Used as long-term maintenance therapy; AND<br>ent's tumor has been visualized on imaging studies (i.e., MRI or CT-scan); AND"<br>Thymic Carcinomas/Thymomas<br>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"<br>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.