Sandostatin® LAR (octreotide suspension)

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I. Length of Authorization

Oncology: Coverage is provided for 6 months and may be renewed at 6 month intervals.

Non-oncology: Coverage is provided for 6 months and may be renewed annually.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Sandostatin LAR Depot 10 mg single-use kit: 1 per 28 days
- Sandostatin LAR Depot 20 mg single-use kit: 2 per 28 days
- Sandostatin LAR Depot 30 mg single-use kit: 2 per 28 days

B. Max Units (per dose and over time) [HCPCS Unit]:

- Carcinoid Tumors and Acromegaly: 40 billable units every 28 days
- Neuroendocrine Tumors: 60 billable units every 28 days
- CNS Cancers and VIPomas: 30 billable units every 28 days
- Thymomas: 20 billable units every 14 days

III. Initial Approval Criteria [1,12,13]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Carcinoid Tumors/Neuroendocrine Tumors (e.g., Gastrointestinal Tract, Lung, Thymus, Pancreas, Adrenal) † ‡ [1,4,6,9]

- Patient has severe diarrhea/flushing episodes (carcinoid syndrome) † Φ; **OR**
- Used as primary treatment for symptom and/or tumor control of unresected primary gastrinoma; **OR**
- Used for symptom and/or tumor control of bronchopulmonary or thymic disease; **AND**

- Used for somatostatin receptor (SSTR) positive disease and/or hormonal symptoms; **AND**
- Used in one of the following treatment settings:
  - Used as primary therapy; **OR**
  - Used as subsequent therapy (as alternate primary therapy) if progression on primary therapy; **OR**
  - Used at above label dosing after disease progression on standard doses *(**Note: Only applies to recurrent and/or metastatic disease);* **OR**
  - Patient has disease progression with functional tumors and will be continuing treatment with octreotide LAR; **AND**
- Patient has one of the following:
  - Recurrent and/or locoregional unresectable disease; **OR**
  - Recurrent and/or distant metastatic disease; **AND**
    - Patient has clinically significant tumor burden and low grade (typical carcinoid) histology; **OR**
    - Patient has evidence of disease progression; **OR**
    - Patient has intermediate grade (atypical carcinoid) histology; **OR**
    - Patient has symptomatic disease; **OR**

- Used for symptom and/or tumor control of multiple lung nodules or tumorlets and evidence of diffuse idiopathic pulmonary neuroendocrine cell hyperplasia (DIPNECH); **AND**
  - Used as primary therapy if chronic cough/dyspnea is not responsive to inhalers or conventional treatment; **OR**
- Used for symptom and/or tumor control of recurrent, locoregional advanced and/or distant metastatic disease of the gastrointestinal tract; **AND**
  - Used as single agent for unresectable disease with a low tumor burden; **OR**
  - Used as a single agent or in combination with alternative front-line therapy if unresectable and patient has a clinically significant tumor burden; **OR**
  - Used as a single agent for disease progression if not already receiving octreotide LAR; **OR**
  - Used as a single agent following resection of primary tumor if unresectable and locally symptomatic from primary tumor; **OR**
  - Used as a single agent as subsequent therapy at above label dosing after clinical, symptomatic, or radiographic progression on standard doses if SSTR-positive; **OR**
  - Patient has disease progression with functional tumors and will be continuing treatment with octreotide LAR; **OR**
- Used for symptom and/or tumor control of somatostatin-receptor positive neuroendocrine tumors of the pancreas (well differentiated grade 1/2); **AND**

- Patient has locoregional gastrinoma, insulinoma, glucagonoma, or VIPoma *(**Note: Somatostatin-receptor positive disease ONLY applies to insulinoma)*; **OR**
- Used as subsequent therapy at above label dosing after clinical, symptomatic or radiographic progression on standard doses; **OR**
- Patient has recurrent or locoregional advanced and/or distant metastatic disease; **AND**
  - Used as a single agent if patient is asymptomatic with a low tumor burden and stable disease; **OR**
  - Patient is symptomatic; **OR**
  - Patient has a clinically significant tumor burden; **OR**
  - Patient has clinically significant progression and is not already receiving octreotide LAR; **OR**
  - Patient has disease progression with functional tumors and will be continuing treatment with octreotide LAR; **OR**

- Patient has pheochromocytoma or paraganglioma; **AND**
  - Used as primary treatment for secreting tumors for symptom and/or tumor control; **AND**
  - Patient has locally unresectable or distant metastatic disease; **OR**
- Patient has well-differentiated grade 3 neuroendocrine tumors; **AND**
  - Used for treatment of symptoms and/or tumor control for somatostatin receptor positive disease and/or hormonal symptoms; **AND**
  - Patient has unresectable locally advanced or metastatic disease with favorable biology (e.g., relatively low Ki-67 [<55%], slow growing, positive SSTR-based PET imaging)

Diarrhea associated with Vasoactive Intestinal Peptide tumors (VIPomas) † Φ [1]

- Patient has profuse watery diarrhea

Acromegaly † Φ [1,3,5,10]

- Patient's diagnosis is confirmed by one of the following:
  - Unequivocally elevated (age-adjusted) serum insulin-like growth factor-1 (IGF-1)
  - Equivocally elevated serum IGF-1 AND inadequate suppression of growth hormone (GH) after a glucose load; **AND**
- Patient has documented inadequate response to surgery and/or radiotherapy or it is not an option for the patient; **AND**
- Used as long-term maintenance therapy; **AND**
- Baseline growth hormone (GH) and IGF-1 blood levels have been obtained (renewal will require reporting of current levels)

Thymomas ‡ [4,8]

- Used with or without prednisone therapy; **AND**
- Patient has a positive octreotide scan or is dotatate PET/CT positive; **AND**
    - Used for patients who are unable to tolerate first-line combination regimens; **AND**
        - Used as first-line therapy for recurrent, advanced, or metastatic disease **OR**
        - Used as preoperative systemic therapy for surgically resectable disease if R0 resection is considered uncertain; **OR**
        - Used as postoperative treatment after R2 resection; **OR**
    - Used as second-line therapy for unresectable locally advanced or metastatic disease

CNS Cancers – Meningiomas ‡ [4,13]

- Used in combination with everolimus; **AND**
- Patient has surgically inaccessible recurrent or progressive disease; **AND**
- Treatment with radiation is not possible

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1,4-9,12]

Coverage can be renewed based on the following criteria:

- Patient continues to meet the indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: cholelithiasis and complications of cholelithiasis (i.e. cholecystitis, cholangitis, pancreatitis), hyperglycemia, hypoglycemia, hypothyroidism, sinus bradycardia, cardiac arrhythmias, cardiac conduction abnormalities, depressed vitamin B_{12} levels, etc.; **AND**
- 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; **AND**
    - **Acromegaly ONLY:** Disease response as indicated by an improvement in signs and symptoms compared to baseline; **AND**
        - Reduction of growth hormone (GH) from pre-treatment baseline; **OR**
        - Age-adjusted normalization of serum IGF-1

V. Dosage/Administration [1,7,13-15]

Indication	Dose
Acromegaly	20 mg intramuscularly§ every 4 weeks for 3 months

	• After 3 months of therapy, doses may be adjusted as follows (not to exceed 40 mg every 4 weeks): ○ GH ≤ 2.5 ng/mL, IGF-1 normal, and clinical symptoms controlled: maintain SANDOSTATIN LAR DEPOT dosage at 20 mg every 4 weeks; **OR** ○ GH > 2.5 ng/mL, IGF-1 elevated, and/or clinical symptoms uncontrolled, increase SANDOSTATIN LAR DEPOT dosage to 30 mg every 4 weeks; **OR** ○ GH ≤ 1 ng/mL, IGF-1 normal, and clinical symptoms controlled, reduce SANDOSTATIN LAR DEPOT dosage to 10 mg every 4 weeks; **OR** ○ If GH, IGF-1, or symptoms are not adequately controlled at a dose of 30 mg, the dose may be increased to 40 mg every 4 weeks
Carcinoid Tumors	20 mg intramuscularly§ every 4 weeks for 2 months • After 2 months of therapy, dosage may be adjusted as follows: ○ If symptoms are not adequately controlled, increase the dose to 30 mg every 4 weeks; **OR** ○ If good control has been achieved on a 20 mg dose, the dose may be lowered to 10 mg for a trial period; if symptoms recur, increase the dose to 20 mg every 4 weeks; **OR** ○ For patients with inadequate symptom control and/or tumor progression, dosage may be increased to 40 mg every 4 weeks
VIPomas	20 mg intramuscularly§ every 4 weeks for 2 months • After 2 months of therapy, dosage may be adjusted as follows: ○ If symptoms are not adequately controlled, increase the dose to 30 mg every 4 weeks; **OR** ○ If good control has been achieved on a 20 mg dose, the dose may be lowered to 10 mg for a trial period; if symptoms recur, increase the dose to 20 mg every 4 weeks
Neuroendocrine Tumors	20 mg intramuscularly§ every 4 weeks for 2 months • After 2 months of therapy, dosage may be adjusted as follows: ○ If symptoms are not adequately controlled, increase the dose to 30 mg every 4 weeks; **OR** ○ If good control has been achieved on a 20 mg dose, the dose may be lowered to 10 mg for a trial period; if symptoms recur, increase the dose to 20 mg every 4 weeks; **OR** ○ For patients with disease progression on standard somatostatin analog doses, dosing of 60 mg every 4 weeks

	may be administered (*excludes adrenal tumors pheochromocytoma/paragangliomas, DIPNECH, and Well-Differentiated Grade 3 Neuroendocrine Tumors*)
Thymomas	20 mg intramuscularly§ every 14 days
CNS Cancers – Meningiomas	30 mg intramuscularly§ every 4 weeks
***Renal impairment (patients on dialysis) and hepatic impairment (patients with cirrhosis): starting dose of 10mg every 4 weeks* *§ SANDOSTATIN LAR DEPOT should never be administered intravenously or subcutaneously*	

VI. Billing Code/Availability Information

HCPCS Code:

- J2353 – Injection, octreotide, depot form for intramuscular injection, 1 mg: 1 mg = 1 billable unit

NDC:

- Sandostatin LAR Depot 10 mg single-use kit: 00078-0811-XX
- Sandostatin LAR Depot 20 mg single-use kit: 00078-0818-XX
- Sandostatin LAR Depot 30 mg single-use kit: 00078-0825-XX

VII. References

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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 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
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
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.8	Other malignant neuroendocrine tumors

ICD-10	ICD-10 Description
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
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
D38.4	Neoplasm of uncertain behavior of thymus
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.094	Benign carcinoid tumor of the foregut, unspecified
D3A.095	Benign carcinoid tumor of the midgut, unspecified
D3A.096	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

ICD-10	ICD-10 Description
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
Z85.238	Personal history of other malignant neoplasm of thymus
Z85.841	Personal history of malignant neoplasm of brain
Z85.848	Personal history of malignant neoplasm of other parts of nervous tissue
Z85.858	Personal history of malignant neoplasm of other endocrine glands

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes		
Jurisdiction	NCD/LCA/LCD Document (s)	Contractor
J, M	A56531	Palmetto GBA

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC