Sandostatin® LAR (octreotide suspension)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months.
- Renewal:
  - Oncology: Prior authorization validity may be renewed every 6 months thereafter.
  - Non-oncology: Prior authorization validity may be renewed every 12 months thereafter.

II. Dosing Limits

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

- Carcinoid Tumors and Acromegaly: 40 billable units every 28 days
- Neuroendocrine and Adrenal Tumors: 60 billable units every 28 days
- CNS Cancers, VIPomas, and Merkel Cell Carcinoma: 30 billable units every 28 days
- Thymomas: 30 billable units every 14 days

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

Prior authorization validity is provided in the following conditions:

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

Carcinoid Tumors/Neuroendocrine and Adrenal Tumors † ‡ [1,4,6,9]

- Patient has severe diarrhea/flushing episodes (carcinoid syndrome) **† Φ**; **OR**
- Used for symptom and/or tumor control of lung 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 first-line therapy; **OR**
    - Used as subsequent therapy (as alternate first-line therapy) if progression on first-line therapy; **OR**

        - Used at above label dosing after disease progression on standard doses *(**Note**: Only applies to recurrent and/or metastatic disease);* **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 control of multiple lung nodules or tumorlets and evidence of diffuse idiopathic pulmonary neuroendocrine cell hyperplasia (DIPNECH); **AND**
    - Used as first-line 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 a single agent if surgical cytoreduction of metastases is not possible and patient has low tumor burden; **OR**
    - Used as a single agent or in combination with alternative front-line therapy if surgical cytoreduction of metastases is not possible and patient has a clinically significant tumor burden; **OR**
    - Used as a single agent for disease progression following resection if not already receiving octreotide LAR; **OR**
    - Used as subsequent therapy as a single agent or in combination with subsequent therapy options for clinically significant disease progression; **OR**
    - Used at above label dosing after clinical, symptomatic, or radiographic progression on standard doses if SSTR-positive; **OR**
- Used for symptom and/or tumor control of neuroendocrine tumors of the pancreas (well differentiated grade 1/2)*; **AND**
    - Patient has locoregional gastrinoma, glucagonoma, Vasoactive Intestinal Peptide tumors (VIPoma), or SSTR-positive insulinoma; **OR**
    - Used at above label dosing after clinical, symptomatic or radiographic progression on standard doses if SSTR-positive; **OR**
    - Patient has recurrent or locoregional advanced and/or distant metastatic disease; **AND**
        - Patient has gastrinoma, glucagonoma, VIPoma, or SSTR-positive insulinoma; **AND**

  - Used as a single agent if patient is asymptomatic with a low tumor burden and stable disease; **OR**
  - Used as a single agent if patient is symptomatic, has clinically significant tumor burden, or has clinically significant progression AND not already receiving octreotide LAR; **OR**
  - Used in combination with alternative front-line therapy for symptomatic, clinically significant tumor burden, or clinically significant progression; **OR**
- Patient has pheochromocytoma or paraganglioma; **AND**
  - Used as treatment of secreting tumors for hormone excess and symptom control; **AND**
  - Patient has locally unresectable or distant metastatic disease; **AND**
  - Patient has SSTR-positive disease; **OR**
- Patient has well-differentiated grade 3 neuroendocrine tumors; **AND**
  - Used for treatment of symptoms and/or tumor control for SSTR-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)

**For clinically significant disease progression, treatment with octreotide LAR should be continued in patients with functional tumors only.*

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); **OR**
  - Equivocally elevated (age-adjusted) 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 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

Merkel Cell Carcinoma ‡ [4,16]

- Used as a single agent for SSTR-positive disease; **AND**
- Patient has progressed on anti-PD-L1 or anti-PD-1 monotherapy OR anti-PD-L1 or anti-PD-1 therapy is contraindicated; **AND**
  - Used for primary N+, M0 regional disease with biopsy positive draining nodal basin if curative surgery and curative radiation therapy (RT) are not feasible; **OR**
  - Used for recurrent N+ regional disease if curative surgery and curative RT are not feasible; **OR**
  - Used for in-transit N+ regional disease

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

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

Prior authorization validity 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 (e.g., cholecystitis, cholangitis, pancreatitis, etc.), hyperglycemia, hypoglycemia, thyroid function abnormalities (hypothyroidism), cardiac function abnormalities (e.g., bradycardia, cardiac arrhythmias, cardiac conduction abnormalities), malabsorption of dietary fats (steatorrhea, stool discoloration, loose stools, etc.), depressed vitamin B_{12} levels, etc.; **AND**

Acromegaly

- 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

Neuroendocrine and Adrenal Tumors

- 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**
- Patient has had disease progression and therapy will be continued in patients with functional tumors

All Other Indications

- 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

V. Dosage/Administration [1,7,13-15,17,18]

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 and Adrenal 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 up to 60 mg every 4 weeks may be administered (*excludes pheochromocytoma/paragangliomas, DIPNECH, and Well-Differentiated Grade 3 Neuroendocrine Tumors*)
Thymomas	Up to 30 mg intramuscularly**§** every 14 days
CNS Cancers – Meningiomas	30 mg intramuscularly**§** every 4 weeks
Merkel Cell Carcinoma	Up to 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 billable unit = 1 mg

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

**Available generically*

VII. References

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Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C25.4	Malignant neoplasm of endocrine pancreas
C37	Malignant neoplasm of thymus
C4A.0	Merkel cell carcinoma of lip
C4A.10	Merkel cell carcinoma of unspecified eyelid, including canthus
C4A.111	Merkel cell carcinoma of right upper eyelid, including canthus
C4A.112	Merkel cell carcinoma of right lower eyelid, including canthus
C4A.121	Merkel cell carcinoma of left upper eyelid, including canthus
C4A.122	Merkel cell carcinoma of left lower eyelid, including canthus
C4A.20	Merkel cell carcinoma of unspecified ear and external auricular canal
C4A.21	Merkel cell carcinoma of right ear and external auricular canal
C4A.22	Merkel cell carcinoma of left ear and external auricular canal
C4A.30	Merkel cell carcinoma of unspecified part of face
C4A.31	Merkel cell carcinoma of nose
C4A.39	Merkel cell carcinoma of other parts of face
C4A.4	Merkel cell carcinoma of scalp and neck
C4A.51	Merkel cell carcinoma of anal skin
C4A.52	Merkel cell carcinoma of skin of breast
C4A.59	Merkel cell carcinoma of other part of trunk
C4A.60	Merkel cell carcinoma of unspecified upper limb, including shoulder
C4A.61	Merkel cell carcinoma of right upper limb, including shoulder
C4A.62	Merkel cell carcinoma of left upper limb, including shoulder
C4A.70	Merkel cell carcinoma of unspecified lower limb, including hip
C4A.71	Merkel cell carcinoma of right lower limb, including hip
C4A.72	Merkel cell carcinoma of left lower limb, including hip
C4A.8	Merkel cell carcinoma of overlapping sites

ICD-10	ICD-10 Description
C4A.9	Merkel cell carcinoma, unspecified
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
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

ICD-10	ICD-10 Description
C7B.09	Secondary carcinoid tumors of other sites
C7B.1	Secondary Merkel cell carcinoma
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
E22.0	Acromegaly and pituitary gigantism
E34.00	Carcinoid syndrome, unspecified
E34.01	Carcinoid heart syndrome

ICD-10	ICD-10 Description
E34.09	Other 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
Z85.821	Personal history of Merkel cell carcinoma
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)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
N (9)	FL, PR, VI	First Coast Service Options, Inc.
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