MEDICAL POLICY

Capital BLUE

POLICY TITLE	SOMATOSTATIN ANALOGUES (LANREOTIDE AND OCTREOTIDE)
POLICY NUMBER	MP-2.130

Original Issue Date (Created):	**August 6, 2007**
Most Recent Review Date (Revised):	**September 24, 2013**
Effective Date:	**November 1, 2013**

I. POLICY

FDA Labeled Indications

Octreotide acetate (Sandostatin®, Sandostatin LAR® Depot) may be considered **medically necessary** for the following FDA labeled indications:

- For treatment of acromegaly in patients who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses.
- 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.
- For the treatment of the profuse watery diarrhea associated with VIP-secreting tumors.

Lanreotide (Somatuline® Depot) may be considered **medically necessary** for the following FDA approved indication: long-term treatment of acromegalic patients who have had an inadequate response to or cannot be treated with surgery and/or radiotherapy.

Off-label Indications

Octreotide acetate (Sandostatin®, Sandostatin LAR® Depot) may be considered **medically necessary** for the following off-label indications:

- To reduce the incidence and severity of the postoperative complications of high-risk pancreatic surgery (e.g., abscess formation and subsequent sepsis, acute pancreatitis, pancreatic fistula, and pancreatic fluid collection)
- To control bleeding and early rebleeding and to reduce transfusion requirements in patients with bleeding gastroesophageal varices associated with cirrhosis when used in combination with an appropriate adjunctive therapeutic intervention such as sclerotherapy;
- To reverse life-threatening hypotension due to carcinoid crisis during induction of anesthesia;
- For use as palliative treatment of the symptoms resulting from hyperinsulinemia due to severe refractory metastatic insulinoma;

- For AIDS patients with severe secretory diarrhea who have failed to respond to antimicrobial or antimotility agents;
- For the treatment of chemotherapy-induced diarrhea (CID); and
- For acute or chronic gastrointestinal blood loss due to angiodysplasia or AV malformation.
- For management of gastrointestinal symptoms (e.g. nausea, vomiting and pain) of in-operable bowel obstruction in persons with terminal cancer.

Octreotide acetate (Sandostatin®, Sandostatin LAR® Depot) and lanreotide (Somatuline® Depot) are considered **investigational** for all other indications not addressed in the policy. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with use for any other indications.

II. PRODUCT VARIATIONS

[N] = No product variation, policy applies as stated
[Y] = Standard product coverage varies from application of this policy, see below

[N] Capital Cares 4 Kids

[N] PPO

[N] HMO

[N] SeniorBlue HMO (see note)

[N] SeniorBlue PPO (see note)

[N] Indemnity

[N] SpecialCare

[N] POS

[N] FEP PPO

Note: "FDA approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if determined that the use is medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice." Refer to Medicare Benefit Policy Manual (100-2, Chapter 15, Section 50.4.2- Unlabeled Use of Drug)."
http://www.cms.gov/manuals/Downloads/bp102c15.pdf

III. DESCRIPTION/BACKGROUND

Somatostatin is a natural peptide that regulates and inhibits the release of hormones by many different neuroendocrine cells in the brain, pancreas, and gastrointestinal tract. Somatostatin inhibits gastric motility and gastric acid secretion, blocks the exocrine and endocrine function of the pancreas, and inhibits the growth and release of hormones by

neuroendocrine tumors. Somatostatin analogues are synthetic compounds that mimic the action of somatostatin. Lanreotide (Somatuline® Depot) and Octreotide (Sandostatin®, Sandostatin LAR® Depot) exert potent inhibitory effects on the secretion of growth hormone (GH), insulin growth factor (IGF-1) and gastrointestinal hormones.

The U.S. Food and Drug Administration (FDA) approved Lanreotide for the long-term treatment of patients with acromegaly who have had an inadequate response or cannot be treated with surgery and/or radiotherapy. It is administered by deep subcutaneous injection.

Octreotide has been FDA approved for the treatment of acromegaly in patients who have had an inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses. In addition, it is approved for the symptomatic treatment of patients with severe diarrhea/flushing episodes associated with metastatic carcinoid tumors and profuse watery diarrhea associated with vasoactive intestinal peptide tumors (VIPomas). Octreotide is available in a short acting form (Sandostatin®) that is administered subcutaneously or intravenously and a long-acting form (Sandostatin LAR® Depot) administered as a deep intramuscular injection.

IV. DEFINITIONS

ACROMEGALY -A condition that results from the excess production of growth hormone in the anterior lobe of the pituitary gland. Acromegaly is characterized by enlarged facial features, enlarged jaw, enlarged frontal bone of skull, widely spaced teeth and enlargement of the bones of the extremities. Other features include enlargement of the lips and nose, thickening of the soft tissues of the face, somnolence, moodiness and decreased libido.

CARCINOID TUMOR -A tumor, which secretes excessive amounts of the hormone serotonin. The clinical result is carcinoid syndrome. These tumors may grow anywhere in the gastrointestinal tract (and in the lungs) with approximately 90% in the appendix. The remainder occur in the ileum, stomach, colon or rectum.

VIPOMA- A rare form of neuroendocrine tumor that causes watery diarrhea, hypokalemia, and achlorhydria as a result of the release of vasoactive intestinal peptide.

V. BENEFIT VARIATIONS

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital for benefit information.

VI. DISCLAIMER

Capital's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VII. REFERENCES

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VIII. CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

HCPCS Code	Description
J1930	INJECTION, LANREOTIDE, 1 MG
J2353	INJECTION, OCTREOTIDE, DEPOT FORM FOR INTRAMUSCULAR INJECTION, 1 MG
J2354	INJECTION, OCTREOTIDE, NON-DEPOT FORM FOR SUBCUTANEOUS OR INTRAVENOUS INJECTION, 25 MCG

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ICD-9-CM Diagnosis Code*	Description
042	HUMAN IMMUNODEFICIENCY VIRUS [HIV]
151.0-151.9	MALIGNANT NEOPLASM OF CARDIA
152.0-152.9	MALIGNANT NEOPLASM OF DUODENUM
153.0-153.9	MALIGNANT NEOPLASM OF HEPATIC FLEXURE
154.0-154.9	MALIGNANT NEOPLASM OF RECTOSIGMOID JUNCTION
155.0-155.2	MALIGNANT NEOPLASM OF LIVER, PRIMARY
156.0-156.9	MALIGNANT NEOPLASM OF GALLBLADDER
157.0-157.9	MALIGNANT NEOPLASM OF HEAD OF PANCREAS
158.0-158.9	MALIGNANT NEOPLASM OF RETROPERITONEUM
159.0-159.9	MALIGNANT NEOPLASM OF INTESTINAL TRACT, PART UNSPECIFIED
162.2-162.9	MALIGNANT NEOPLASM OF MAIN BRONCHUS
191.0-191.9	MALIGNANT NEOPLASM OF CEREBRUM, EXCEPT LOBES AND VENTRICLES
192.0-192.9	MALIGNANT NEOPLASM OF CRANIAL NERVES

ICD-9-CM Diagnosis Code*	Description
194.0	MALIGNANT NEOPLASM OF ADRENAL GLAND
197.0	SECONDARY MALIGNANT NEOPLASM OF LUNG
197.4	SECONDARY MALIGNANT NEOPLASM OF SMALL INTESTINE INCLUDING DUODENUM
197.5	SECONDARY MALIGNANT NEOPLASM OF LARGE INTESTINE AND RECTUM
197.6	SECONDARY MALIGNANT NEOPLASM OF RETROPERITONEUM AND PERITONEUM
197.7	SECONDARY MALIGNANT NEOPLASM OF LIVER
197.8	SECONDARY MALIGNANT NEOPLASM OF OTHER DIGESTIVE ORGANS AND SPLEEN
209.0-209.69	MALIGNANT CARCINOID TUMORS OF THE SMALL INTESTINE
211.6	BENIGN NEOPLASM OF PANCREAS, EXCEPT ISLETS OF LANGERHANS
211.7	BENIGN NEOPLASM OF ISLETS OF LANGERHANS
227.3	BENIGN NEOPLASM OF PITUITARY GLAND AND CRANIOPHARYNGEAL DUCT (POUCH)
253.0	ACROMEGALY AND GIGANTISM
259.2	CARCINOID SYNDROME
456.20	ESOPHAGEAL VARICES WITH BLEEDING IN DISEASES CLASSIFIED ELSEWHERE
537.82	ANGIODYSPLASIA OF STOMACH AND DUODENUM (WITHOUT MENTION OF HEMORRHAGE)
537.83	ANGIODYSPLASIA OF STOMACH AND DUODENUM WITH HEMORRHAGE
537.84	DIEULAFOY LESION (HEMORRHAGIC) OF STOMACH AND DUODENUM
569.84	ANGIODYSPLASIA OF INTESTINE (WITHOUT MENTION OF HEMORRHAGE)
569.85	ANGIODYSPLASIA OF INTESTINE WITH HEMORRHAGE
569.86	DIEULAFOY LESION (HEMORRHAGIC) OF INTESTINE
571.0-571.9	ALCOHOLIC FATTY LIVER
577.0-577.9	ACUTE PANCREATITIS
747.61	CONGENITAL GASTROINTESTINAL VESSEL ANOMALY
751.7	CONGENITAL ANOMALIES OF PANCREAS
787.91	DIARRHEA
863.81-863.84	PANCREAS HEAD INJURY WITHOUT MENTION OF OPEN WOUND INTO CAVITY
995.20	UNSPECIFIED ADVERSE EFFECT OF UNSPECIFIED DRUG, MEDICINAL AND BIOLOGICAL SUBSTANCE
995.29	UNSPECIFIED ADVERSE EFFECT OF OTHER DRUG, MEDICINAL AND BIOLOGICAL SUBSTANCE
996.86	COMPLICATIONS OF TRANSPLANTED PANCREAS
V58.11	ENCOUNTER FOR ANTINEOPLASTIC CHEMOTHERAPY

**If applicable, please see Medicare LCD or NCD for additional covered diagnoses.*

IX. POLICY HISTORY

MP-2.130	**CAC 3/27/07** (New Policy)
	CAC 3/25/08 Consensus
	CAC 9/29/09
	CAC 11/30/10 Consensus review
	CAC 11/22/11 Consensus review
	CAC 9/24/13 Consensus review. No change to policy statements. References reviewed and updated.
	7/26/13 Admin coding review complete

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