POLICY Document for SANDOSTATIN LAR DEPOT (octreotide acetate for injectable suspension)

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, and overall, clinically appropriate use. This document provides specific information to both sections of the overall policy.

Section 1: Clinical Criteria

- Policy information specific to the clinical appropriateness for the medication

Section 2: Oncology Clinical Policy

- Policy information specific to regimen review per NCCN Guidelines.

Section 1: Clinical Criteria

Specialty Guideline Management octreotide products

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Sandostatin	octreotide acetate injection
Bynfezia Pen	octreotide acetate injection
Mycapssa	octreotide delayed-release capsule
Sandostatin LAR Depot	octreotide acetate for injectable suspension

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1-3,37,38,40]

Sandostatin/Bynfezia Pen/ octreotide acetate injection:
Indicated to reduce blood levels of growth hormone (GH) and insulin growth factor-1 (IGF-1; somatomedin C) in acromegaly patients who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses.
Indicated 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.
Indicated for the treatment of the profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors.
Sandostatin LAR/octreotide acetate for injectable suspension: Sandostatin LAR Depot and octreotide acetate for injectable suspension are indicated in patients who have responded to and tolerated Sandostatin Injection/octreotide acetate injection for:
Long-term maintenance therapy in acromegalic patients who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option. The goal of treatment in acromegaly is to reduce GH and IGF-1 levels to normal.
Long-term treatment of the severe diarrhea and flushing episodes associated with metastatic carcinoid tumors.
Long-term treatment of the profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors.
Limitations of Use:
In patients with carcinoid syndrome and VIPomas, the effect of Sandostatin Injection and Sandostatin LAR Depot on tumor size, rate of growth and development of metastases, has not been determined.
Mycapssa is indicated for long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide.

Compendial Uses (applies to injectable products)

Neuroendocrine tumors (NETs):[4,39]
Tumors of the gastrointestinal (GI) tract, lung, and thymus (carcinoid tumors)
Tumors of the pancreas (islet cell tumors)
Gastroenteropancreatic neuroendocrine tumors (GEP-NETs)
Pheochromocytoma and paraganglioma[4]
Thymomas and thymic carcinomas[4,34]
Congenital hyperinsulinism (CHI)/persistent hyperinsulinemic hypoglycemia of infancy (PHHI)(octreotide and Sandostatin only)
Acquired immune deficiency syndrome (AIDS)-associated diarrhea[12,13,31]
Inoperable bowel obstruction[14-16,32]
Cancer-related diarrhea[11]
Enterocutaneous fistula[17-19,26]
Gastroesophageal varices[20-25]
Pancreatic fistulas[27-29,35.36]
Pituitary adenoma[9,30]

Short bowel syndrome[12,31,333]
Zollinger-Ellison syndrome[7]
Meningiomas[4]
All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

For acromegaly:
For initial approval: Laboratory report indicating high pretreatment insulin-like growth factor-1 (IGF-1) level and chart notes indicating an inadequate or partial response to surgery or radiotherapy or a clinical reason for not having surgery or radiotherapy.
For continuation: Laboratory report indicating normal current IGF-1 levels or chart notes indicating that the member's IGF-1 level has decreased or normalized since initiation of therapy.
Cancer-related diarrhea: Chart notes indicating grade 3 or 4 diarrhea.

Coverage Criteria

Acromegaly[1-3,5,6,37,38,40]

Authorization of 12 months may be granted for the treatment of acromegaly when all of the following criteria are met:

Member has a high pretreatment IGF-1 level for age and/or gender based on the laboratory reference range.
Member had an inadequate or partial response to surgery or radiotherapy OR there is a clinical reason why the member has not had surgery or radiotherapy.
For Mycapssa requests, member has previously responded to and tolerated treatment with octreotide or lanreotide.

Neuroendocrine Tumors (NETs) (injectable products only)[1-4,7,8,37,39,40]

Authorization of 12 months may be granted for treatment of NETs of the gastrointestinal (GI) tract, lung, and thymus (carcinoid tumors).
Authorization of 12 months may be granted for treatment of NETs of the pancreas (islet cell tumors), including gastrinomas, glucagonomas, and insulinomas.
Authorization of 12 months may be granted for treatment of gastroenteropancreatic neuroendocrine tumors (GEP-NETs).

Carcinoid Syndrome (injectable products only)[1-4,7,37,40]

Authorization of 12 months may be granted for treatment of carcinoid syndrome.

Vasoactive Intestinal Peptide Tumors (VIPomas) (injectable products only)[1-4,7,37,40]

Authorization of 12 months may be granted for management of symptoms related to hormone hypersecretion of VIPomas.

Pheochromocytoma and Paraganglioma (injectable products only)[4]

Authorization of 12 months may be granted for treatment of pheochromocytoma and paraganglioma.

Thymomas and Thymic Carcinomas (injectable products only)[4,10,34]

Authorization of 12 months may be granted for treatment of thymomas and thymic carcinomas.

Congenital Hyperinsulinism (CHI)/Persistent Hyperinsulinemic Hypoglycemia of Infancy (octreotide and Sandostatin only)

Authorization of 6 months may be granted for treatment of CHI and persistent hyperinsulinemic hypoglycemia in an infant.

AIDS-Associated Diarrhea (injectable products only)[13]

Authorization of 12 months may be granted for treatment of AIDS-associated severe secretory diarrhea when anti-microbial (e.g., ciprofloxacin or metronidazole) or anti-motility agents (e.g., loperamide or diphenoxylate and atropine) have become ineffective.

Inoperable Bowel Obstruction in Cancer (injectable products only)[11,14-16,32]

Authorization of 12 months may be granted for management of GI symptoms (e.g., nausea, pain, vomiting) of inoperable bowel obstruction in members with cancer.

Cancer-Related Diarrhea (injectable products only)[11]

Authorization of 12 months may be granted for treatment of cancer-related diarrhea when the member has grade 3 or greater diarrhea according to National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE).

Enterocutaneous Fistula (injectable products only)[17-19,26]

Authorization of 12 months may be granted for management of volume depletion from enterocutaneous fistula.

Gastroesophageal Varices (injectable products only)[20-25]

Authorization of 6 months may be granted for treatment of acute bleeding of gastroesophageal varices associated with cirrhosis.

Pancreatic Fistulas (injectable products only)[27-29,35,36]

Authorization of 6 months may be granted for prevention and treatment of pancreatic fistulas following pancreatic surgery.

Pituitary Adenoma (injectable products only)[9,30]

Authorization of 12 months may be granted for treatment of pituitary adenoma.

Short Bowel Syndrome (injectable products only)[12,31,33]

Authorization of 12 months may be grated for treatment of short bowel syndrome when the daily intravenous fluid requirement is greater than 3 liters.

Zollinger-Ellison Syndrome (injectable products only)[7]

Authorization of 12 months may be grated for treatment of Zollinger-Ellison syndrome.

Meningiomas (injectable products only)[4]

Authorization of 12 months may be granted for treatment of meningiomas when used in combination with everolimus for surgically inaccessible recurrent or progressive disease.

Continuation of Therapy

Acromegaly

Authorization of 12 months may be granted for continuation of therapy for acromegaly when the member's IGF-1 level has decreased or normalized since initiation of therapy.

NETs, Carcinoid Syndrome, Vipomas, Pheochromocytoma/Paraganglioma, Thymomas/Thymic Carcinomas, AIDS-Associated Diarrhea, Bowel Obstruction, Cancer-Related Diarrhea, Zollinger-Ellison Syndrome, and Meningiomas (injectable products only)

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when the member is experiencing clinical benefit as evidenced by improvement or stabilization in clinical signs and symptoms since initiation of therapy.

All Other Indications

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

Section 2: Oncology Clinical Policy

PURPOSE

The purpose of this policy is to define the Novologix NCCN® Regimen Prior Authorization Program.

SCOPE

This policy applies to clients who have implemented the Novologix NCCN® Program as a part of their medical and/or pharmacy prior authorization solution.

PROGRAM DESCRIPTION

The National Comprehensive Care Network® (NCCN®) is an alliance of leading cancer centers devoted to patient care, research and education dedicated to improving the quality, effectiveness, and efficiency of cancer care so patients can live better lives.[1] It is comprised of oncology experts who convene regularly to establish the best treatments for patients. NCCN develops various resources for use by stakeholders in the health care delivery system. These resources include, but are not limited to, the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®), the NCCN Drugs & Biologics Compendium (NCCN Compendium®) and the NCCN Chemotherapy Order Templates (NCCN Templates®).

NCCN Templates® are based on NCCN Guidelines® and NCCN Compendium®. The NCCN Compendium lists the appropriate drugs and biologics as treatment options for specific cancers using U.S. Food and Drug Administration (FDA)-approved disease indications and specific NCCN panel recommendations. Each recommendation is supported by a level of evidence category.

NCCN Categories of Evidence and Consensus[2]

- Category 1: Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
- Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.

• Category 2B: Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
• Category 3: Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

POLICY

Policy for Regimen Prior Authorization
A regimen prior authorization allows submission of a single prior authorization request for all oncology drugs or biologics within an NCCN template that require prior authorization.

PROCEDURE

This policy provides coverage of a regimen review when all of the following criteria are met:
1. Regimen prior authorization reviews, based on NCCN templates, are initiated through the provider portal.
- If the prior authorization request is submitted via phone or fax, each drug or biologic will need to be submitted and reviewed as a separate prior authorization request for review with drug-specific criteria.

2. The prior authorization review is requested for an oncology drug or biologic.
3. The member is eligible for regimen review.
4. The indication is for a cancer that is eligible for regimen review. Currently, the cancer types in scope for regimen review include the following:
    - Ampullary Adenocarcinoma
    - Anal Carcinoma
    - B-Cell Lymphomas
    - Basal Cell Skin Cancer
    - Biliary Tract Cancers
    - Bone Cancer
    - Breast Cancer
    - Bladder Cancer
    - Central Nervous System Cancers
    - Cervical Cancer
    - Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
    - Chronic Myeloid leukemia
    - Colon Cancer
    - Dermatofibrosarcoma Protuberans
    - Esophageal Cancer
    - Gastric Cancer
    - Gastrointestinal Stromal Tumors

- Gestational Trophoblastic Neoplasms
- Hairy Cell Leukemia
- Head and Neck Cancers
- Histiocytic Neoplasms
- Hodgkin Lymphoma
- Hepatocellular Carcinoma
- Kaposi Sarcoma
- Kidney Cancer
- Melanoma: Cutaneous
- Melanoma: Uveal
- Merkel Cell Carcinoma
- Mesothelioma: Peritoneal
- Mesothelioma: Pleural
- Multiple Myeloma
- Myelodysplastic Syndromes
- Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions
- Myeloproliferative Neoplasms
- Neuroendocrine and Adrenal Tumors
- Non-Small Cell Lung Cancer
- Occult Primary
- Ovarian Cancer
- Pancreatic Cancer
- Penile Cancer
- Primary Cutaneous Lymphomas
- Prostate Cancer
- Rectal Cancer
- Small Bowl Adenocarcinoma
- Small Cell Lung Cancer
- Soft Tissue Sarcoma
- Squamous Cell Skin Cancer
- Systemic Mastocytosis
- Systemic Light Chain Amyloidosis
- T-Cell Lymphomas
- Testicular Cancer
- Thymomas and Thymic Carcinomas
- Thyroid Carcinoma
- Uterine Neoplasms
- Vaginal Cancer
- Vulvar Cancer

- Waldenström Macroglobulinemia / Lymphoplasmacytic Lymphoma
- Wilms Tumor (Nephroblastoma)

In addition, the following criteria must be met for approval:

1. The requested regimen for the drug(s) or biologic(s) and indication is consistent with an NCCN recommendation with a level of evidence category of 1 or 2A.
2. The NCCN template must be accepted by the provider without modification.

Further review may be indicated when the above criteria are not met.

Authorizations may be granted for 12 months or as medically required, based on the member's condition and provider's assessment.

Supportive Care: Myeloid Growth Factor Therapy

Granulocyte colony stimulating factors are recommended for primary prophylaxis based on the febrile neutropenia risk of the chemotherapy regimen. Febrile neutropenia risk levels vary by NCCN Chemotherapy Order template and are listed at the top of the template. Regimens associated with a high or intermediate risk of febrile neutropenia may include a granulocyte colony stimulating factor as part of the prior authorization.

Continuation of Therapy

To submit a request for continuation of therapy, a new regimen prior authorization review must be requested. Upon template selection, the template must be modified to include the appropriate therapies being used for maintenance treatment. The regimen request will be submitted for further review.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and evidence-based practice guidelines.

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SECTION 2

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