



Octreotide Suspension (Sandostatin® LAR Depot), Octreotide Acetate for Injectable Suspension

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:

POLICY

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

Sandostatin LAR Depot, octreotide acetate for injectable suspension

- ~~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~~ **Indicated in patients in whom initial treatment with Sandostatin Injection/octreotide acetate injection has been shown to be effective and tolerated 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 (**VIPomas**).

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.

Compendial Uses

- Neuroendocrine **and adrenal** tumors (NETs):
 - 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
- Thymomas ~~and thymic carcinomas~~
- Meningiomas
- **Merkel cell carcinoma**
- Cancer-related diarrhea



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- Inoperable **malignant** bowel obstruction
- Acquired immune deficiency syndrome (AIDS)-associated diarrhea
- Enterocutaneous fistula
- Pancreatic fistulas
- Gastroesophageal varices
- Pituitary adenoma
- Short bowel syndrome
- Zollinger-Ellison syndrome

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 that~~ surgery or radiotherapy **are not an option.**
 - 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.
- **For cancer-related diarrhea:** Chart notes indicating grade 3 or 4 diarrhea.

COVERAGE CRITERIA

Acromegaly

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 meets one of the following:**
 - 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.~~
 - **Surgery or radiotherapy are not an option for the member.**

Neuroendocrine Tumors (NETs)

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

Carcinoid Syndrome

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



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Vasoactive Intestinal Peptide Tumors (VIPomas)

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

~~Pheochromocytoma and Paraganglioma~~

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

~~Thymomas and Thymic Carcinomas~~

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

Meningiomas

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

Merkel Cell Carcinoma

Authorization of 12 months may be granted for treatment of somatostatin receptor-positive Merkel cell carcinoma as a single agent when the member has a contraindication to anti-PD-L1 and anti-PD-1 therapy and one of the following criteria is met:

- The member has regional disease.
- The member has disease progression while on anti-PD-L1 or anti-PD-1 therapy.

Cancer-Related Diarrhea

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

Inoperable Malignant Bowel Obstruction in Cancer

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.

AIDS-Associated Diarrhea

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.

Enterocutaneous Fistula

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

Pancreatic Fistulas

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



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Gastroesophageal Varices

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

Pituitary Adenoma

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

Short Bowel Syndrome

Authorization of 12 months may be granted for treatment of short bowel syndrome ~~when the daily intravenous fluid requirement is greater than 3 liters~~ in members with large volume stool losses when fluid and electrolyte management is problematic.

Zollinger-Ellison Syndrome

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

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, Meningiomas, Merkel Cell Carcinoma, Cancer-Related Diarrhea, Inoperable Malignant Bowel Obstruction, AIDS-Associated Diarrhea, and Zollinger-Ellison Syndrome and Meningiomas

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.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

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For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

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EFFECTIVE DATE

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