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PHARMACY POLICY STATEMENT
Mississippi Medicaid

DRUG NAME	Somatostatin analogs (Injectable; First generation): Sandostatin (octreotide), Sandostatin LAR (octreotide), Somatuline Depot (lanreotide)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

The four injectable first-generation somatostatin analogs approved are Sandostatin, Sandostatin LAR, Somatuline Depot and Bynfezia. They treat multiple conditions including acromegaly, carcinoid syndrome, vasoactive intestinal peptide tumor (VIPoma) and gastroenteropancreatic neuroendocrine tumors (GEP-NETs).
Acromegaly is typically the result of a GH-secreting pituitary adenoma, thus surgical resection is the preferred treatment whenever possible. If disease persists after surgery or surgery is not possible, a first-generation long-acting somatostatin receptor ligand is recommended as first-line therapy. The goal of treatment is to reduce growth hormone (GH) and insulin growth factor-1 (IGF-1) levels to normal, with IGF-1 as the best reflection of disease control.
Carcinoid syndrome refers to a collection of symptoms that primarily occurs with well-differentiated neuroendocrine tumors (NETs) originating midgut with metastases to the liver. Flushing and diarrhea are the most common manifestations. Somatostatin analogs are typically the first line approach to alleviate symptoms.

Somatostatin analogs (Injectable; First generation) will be considered for coverage when the following criteria are met:

Acromegaly

For **initial** authorization:
1. Member is 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with an endocrinologist; AND
3. Member has diagnosis of uncontrolled acromegaly confirmed by insulin-like growth factor (IGF-1) elevation above normal level (lab report required); AND
4. Member had an inadequate response to surgery or member is ineligible for these treatments (documentation required); AND
5. For Somatuline Depot only: must have a trial and failure of Sandostatin LAR.
6. For Bynfezia only:
   a) Baseline thyroid function testing is required; AND
   b) Trial and failure of short acting octreotide (generic Sandostatin).
7. **Dosage allowed/Quantity limit:**
   Octreotide: initial dose of 50 mcg subcutaneously or intravenously three times daily for two weeks. Titrate per GH/IGF-1 levels up to maximum dose of 500 mcg three times daily. Quantity limit: 84 ampules per 28 days.
   Sandostatin LAR: initial dose of 20 mg intramuscularly every 4 weeks for 3 months. Titrate according to GH and IGF-1 dosing scheme per package insert. The maximum dose is 40 mg every 4 weeks.
   Note: patients not currently on octreotide injections must trial them for two weeks prior to switching to sandostatin LAR per the dosing scheme in the package insert. Quantity limit: 1 kit per 28 days.

Somatuline depot: initial dose of 90 mg subcutaneously every 4 weeks for 3 months. Titrate according to GH and IGF-1 per package insert. The maximum dose is 120 mg every 4 weeks. Quantity limit: 1 syringe per 28 days.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes/lab report must show normalized or improved (decreased) IGF-1.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Carcinoid Syndrome

For **initial** authorization:
1. Member is 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with an oncologist, gastroenterologist or endocrinologist; AND
3. Member has a neuroendocrine tumor, including carcinoid tumor or vasoactive intestinal peptide tumor (VIPoma); AND
4. Member is experiencing flushing and/or diarrhea symptoms associated with carcinoid syndrome (or VIPoma syndrome), not attributed to another cause; AND
5. For Somatuline Depot only: must have a trial and failure of Sandostatin LAR.
6. For Bynfezia only:
   a) Baseline thyroid function testing is required; AND
   b) Trial and failure of short acting octreotide (generic Sandostatin).
7. **Dosage allowed/Quantity limit:**
   Octreotide: inject 100 mcg-750 mcg per day subcutaneously or intravenously in divided doses.
   Sandostatin LAR: inject 20 mg intramuscularly every 4 weeks for two months. Titrate based on symptom control outlined in package insert. The maximum dose is 30 mg every 4 weeks. *Note:* patients not currently on octreotide injections must trial them for two weeks prior to switching to sandostatin LAR per the dosing scheme in the package insert. Quantity limit: 1 kit per 28 days.
   Somatuline depot: inject 120 mg subcutaneously every 4 weeks. Quantity limit: 1 syringe per 28 days.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. For short-acting products (octreotide): chart notes must document symptomatic improvement of flushing and/or diarrhea episodes.
2. For long-acting products (Sandostatin LAR, Somatuline Depot): chart notes must document reduced frequency of short-acting somatostatin analog rescue therapy for symptom control.

If all the above requirements are met, the medication will be approved for an additional 12 months.

NOTE to reviewer: A short-acting product may be used concurrently with a long-acting product.

Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs)

Any request for cancer must be submitted through NantHealth/Eviti portal.

TrueCare considers Somatostatin analogs (Injectable; First generation) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
11/03/2020	New policy for injectable somatostatin analogs created.
04/01/2022	Transferred to new template. Updated references. Added quantity limits to the long-acting products. Acromegaly: Removed note about combination use.
02/07/2025	Updated references; edited medication/disease summary; clarified dosing; added quantity limit for octreotide (for acromegaly only) and Bynfezia. Acromegaly: removed "If IGF-1 elevation is 1.5x upper limit of normal or less, member must have a trial of, or contraindication or intolerance to cabergoline" per Melmed S et al; removed inadequate response to radiation from prior treatment options per Ogedegbe OJ et al; updated Sandostatin LAR quantity limit. CS: added endocrinologist as prescriber specialty option.

References:

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