Endocrine and Metabolic Agents : Somatostatic Agents

WA.PHAR.153 Effective Date: 2/1/2026

Related medical policies:

Policy Number	Policy Name
N/A	

Note: *New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. Non-preferred agents in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class documentation of inadequate response to ONE preferred agent is needed. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.*

To see the list of the current publication of the Coordinated Care of Washington, Inc. Preferred Drug List (PDL), please visit: *https://www.coordinatedcarehealth.com/content/dam/centene/centene-pharmacy/pdl/FORMULARY-CoordinatedCare_Washington.pdf*

Medical necessity

Drug	Medical Necessity
Lanreotide acetate (Somatuline Depot) Octreotide acetate (Mycapssa) Octreotide acetate (Sandostatin) Octreotide acetate Mi-Spheres (Sandostatin LAR Depot) Pasireotide diaspartate (Signifor) Pasireotide pamoate (Signifor LAR)	**Endocrine and Metabolic Agents : Somatostatic Agents** may be considered medically necessary in patients who meet the criteria described in the clinical policy below. • Non-Preferred brand name products on the Apple Health Drug List with an A-rated generic, biosimilar or interchangeable biosimilar must also meet criteria in the WA.PHAR.65 Brands with Biosimilars or A-rated Generic policy. If all criteria are not met, the clinical reviewer may determine there is a medically necessary need and approve on a case-by-case basis. The clinical reviewer may choose to use the reauthorization criteria when a patient has been previously established on therapy and is new to Apple Health.

Clinical policy:

Clinical Criteria	
Acromegaly Lanreotide acetate (Somatuline Depot) Octreotide acetate (Mycapssa) Octreotide acetate (Sandostatin)	Lanreotide acetate (Somatuline Depot), octreotide acetate (Mycapssa) octreotide acetate (Sandostatin), octreotide acetate Mi-Spheres (Sandostatin LAR Depot), or pasireotide pamoate (Signifor LAR) may be approved when all of the following documented criteria are met: 1. Patient is 18 years of age or older, **AND** 2. Prescribed by, or in consultation with, an endocrinologist; **AND**

Octreotide acetate Mi-Spheres (Sandostatin LAR Depot) Pasireotide pamoate (Signifor LAR)	3. Not used in combination with another somatostatic agent (e.g. lanreotide, octreotide); **AND** 4. Diagnosis of acromegaly; **AND** 5. Provider provides attestation that the patient has failed or is not a candidate for surgery to treat acromegaly; **AND** 6. For Mycapssa requests: Documentation of demonstrated response and tolerance to treatment with octreotide or lanreotide; **AND** a. Rationale is provided why the patient is unable to use injectable octreotide or lanreotide. If ALL criteria are met, the request will be authorized for **6 months.** **Criteria (Reauthorization)** Lanreotide acetate (Somatuline Depot), octreotide acetate (Mycapssa) octreotide acetate (Sandostatin), octreotide acetate Mi-Spheres (Sandostatin LAR Depot), or pasireotide pamoate (Signifor LAR) may be approved when all the following documented criteria are met: 1. Not used in combination with another somatostatic agent (e.g. lanreotide, octretide); **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response [e.g., normalization of serum IGF-1, normalization of growth hormone, adenoma shrinkage]. If ALL criteria are met, the request will be authorized for **12 months.**
Carcinoid Syndrome Lanreotide acetate (Somatuline Depot) Octreotide acetate (Sandostatin) Octreotide acetate Mi-Spheres (Sandostatin LAR Depot)	Lanreotide acetate (Somatuline Depot), octreotide acetate (Sandostatin), or octreotide acetate Mi-Spheres (Sandostatin LAR Depot) may be approved when all the following documented criteria are met: 1. Patient is 18 years of age or older, **AND** 2. Not used in combination with another somatostatic agent (e.g. lanreotide, octreotide); **AND** 3. Diagnosis of carcinoid syndrome; **AND** 4. Patient is experiencing symptoms related to carcinoid syndrome (e.g., diarrhea, flushing). If ALL criteria are met, the request will be authorized for **6 months.** **Criteria (Reauthorization)** Lanreotide acetate (Somatuline Depot), octreotide acetate (Sandostatin), or octreotide acetate Mi-Spheres (Sandostatin LAR Depot) may be approved when all the following documented criteria are met: 1. Not used in combination with another somatostatic agent (e.g. lanreotide, octreotide); **AND**

	2. Documentation is submitted demonstrating disease stability or a positive clinical response [e.g., improvement of flushing, improvement of diarrhea, etc.]. If ALL criteria are met, the request will be authorized for **12 months.**
Cushing's Syndrome Pasireotide diaspartate (Signifor) Pasireotide pamoate (Signifor LAR)	Pasireotide diaspartate (Signifor) or pasireotide pamoate (Signifor LAR) may be approved when all the following documented criteria are met: 1. Patient is 18 years of age or older, **AND** 2. Prescribed by, or in consultation with, an endocrinologist; **AND** 3. Not used in combination with another somatostatic agent (e.g. lanreotide, octreotide); **AND** 4. Diagnosis of Cushing's Syndrome; **AND** 5. Provider submits attestation that the patient has failed or is not a candidate for surgery to treat Cushing's Syndrome. If ALL criteria are met, the request will be authorized for **6 months.**
	Criteria (Reauthorization) Pasireotide diaspartate (Signifor) or pasireotide pamoate (Signifor LAR) may be approved when all the following documented criteria are met: 1. Not used in combination with another somatostatic agent (e.g. lanreotide, octreotide); **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response [e.g., reduction in tumor volume, decrease in urine free cortisol]. If ALL criteria are met, the request will be authorized for **12 months.**
Diarrhea, chemotherapy-induced, severe or persistent Octreotide acetate (Sandostatin)	Octreotide acetate (Sandostatin) may be approved when all the following documented criteria are met: 1. Patient is 18 years of age or older, **AND** 2. Not used in combination with another somatostatic agent (e.g. lanreotide, octreotide); **AND** 3. Diagnosis of severe or persistent diarrhea due to chemotherapy; **AND** 4. History of failure, contraindication, or intolerance to loperamide. If ALL criteria are met, the request will be authorized for **6 months.**
	Criteria (Reauthorization) Octreotide acetate (Sandostatin) may be approved when all the following documented criteria are met: 1. Not used in combination with another somatostatic agent (e.g. lanreotide, octreotide); **AND**

	2. Documentation is submitted demonstrating disease stability or a positive clinical response [e.g., decrease in frequency of bowel movements from baseline]. If ALL criteria are met, the request will be authorized for **12 months.**
Vasoactive intestinal peptide-secreting tumor, associated diarrhea Octreotide acetate (Sandostatin) Octreotide acetate Mi-Spheres (Sandostatin LAR Depot)	Octreotide acetate (Sandostatin) or octreotide acetate Mi-Spheres (Sandostatin LAR Depot) may be approved when all the following documented criteria are met: 1. Patient is 18 years of age or older, **AND** 2. Not used in combination with another somatostatic agent (e.g. lanreotide, octreotide); **AND** 3. Diagnosis of vasoactive intestinal peptide-secreting tumor (VIPoma); **AND** 4. Request is prescribed for the management of diarrhea due to VIPoma. If ALL criteria are met, the request will be authorized for **6 months.** **Criteria (Reauthorization)** Octreotide acetate (Sandostatin) or octreotide acetate Mi-Spheres (Sandostatin LAR Depot) may be approved when all the following documented criteria are met: 1. Not used in combination with another somatostatic agent (e.g. lanreotide, octreotide); **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response [e.g., reduction in use of rescue therapy, decrease in frequency of bowel movements from baseline]. If ALL criteria are met, the request will be authorized for **12 months.**
Well-differentiated neuroendocrine tumor, gastroenteropancreatic Lanreotide acetate (Somatuline Depot)	Lanreotide acetate (Somatuline Depot) may be approved when all the following documented criteria are met: 1. Patient is 18 years of age or older, **AND** 2. Prescribed by, or in consultation with, an oncologist; **AND** 3. Not used in combination with another somatostatic agent (e.g. lanreotide, octreotide); **AND** 4. Diagnosis of gastroenteropancreatic neuroendocrine tumor that is unresectable, well- or moderately-differentiated, locally advanced or metastatic. If ALL criteria are met, the request will be authorized for **6 months.** **Criteria (Reauthorization)** Lanreotide acetate (Somatuline Depot) may be approved when all the following documented criteria are met: 1. Not used in combination with another somatostatic agent (e.g. lanreotide, octreotide); **AND**

	2. Documentation is submitted demonstrating disease stability or a positive clinical response [e.g., stabilization of disease, decrease in tumor size or tumor spread, lack of disease progression]. If ALL criteria are met, the request will be authorized for **6 months.**

Dosage and quantity limits

Drug	Indication	Approved Dose	Dosage Form and Quantity Limit
Lanreotide acetate (Somatuline Depot)	Acromegaly	Initial: 90 mg every 4 weeks for 3 months Maintenance: Up to 120 mg every 4 weeks	• 60 mg, 90 mg, and 120 mg syringes: 1 syringe every 4 weeks
	Carcinoid Syndrome	120 mg every 4 weeks	• 120 mg syringes: 1 syringe every 4 weeks
	Well-differentiated neuroendocrine tumor, gastroenteropancreatic	120 mg every 4 weeks	• 120 mg syringes: 1 syringe every 4 weeks
Octreotide acetate (Mycapssa)	Acromegaly	Up to 80 mg daily	• 20 mg capsules: 120 capsules every 30 days
Octreotide acetate (Sandostatin)	Acromegaly	Initial: 50 mcg three times daily Maintenance: Up to 500 mcg 3 times daily	• 50 mcg ampules/syringes/vials: 90 every 30 days • 100 mcg ampules/syringes/vials: 90 every 30 days • 500 mcg ampules/syringes/vials: 90 every 30 days • 1000 mcg/5 mL vials: 45 vials every 30 days • 5000 mcg/5 mL vials: 10 vials every 30 days
	Carcinoid Syndrome	Up to 1500 mcg divided in 2 to 4 doses	• 50 mcg ampules/syringes/vials: 90 every 30 days • 100 mcg ampules/syringes/vials: 90 every 30 days • 500 mcg ampules/syringes/vials: 90 every 30 days • 1000 mcg/5 mL vials: 45 vials every 30 days • 5000 mcg/5 mL vials: 10 vials every 30 days
	Diarrhea, chemotherapy-induced, severe or persistent	Up to 500 mcg 3 times daily	• 50 mcg ampules/syringes/vials: 90 every 30 days • 100 mcg ampules/syringes/vials: 90 every 30 days • 500 mcg ampules/syringes/vials: 90 every 30 days

			• 1000 mcg/5 mL vials: 45 vials every 30 days • 5000 mcg/5 mL vials: 10 vials every 30 days
	Vasoactive intestinal peptide-secreting tumor, associated diarrhea	Up to 750 mcg divided in 2 to 4 doses	• 50 mcg ampules/syringes/vials: 90 every 30 days • 100 mcg ampules/syringes/vials: 90 every 30 days • 500 mcg ampules/syringes/vials: 90 every 30 days • 1000 mcg/5 mL vials: 23 vials every 30 days • 5000 mcg/5 mL vials: 5 vials every 30 days
Octreotide acetate mi-spheres (Sandostatin LAR Depot)	Acromegaly	Up to 40 mg every 4 weeks	• 10 mg vials: 1 vial every 4 weeks • 20 mg vials: 2 vials every 4 weeks • 30 mg vials: 1 vial every 4 weeks
	Carcinoid Syndrome	Up to 30 mg every 4 weeks	• 10 mg, 20 mg, and 30 mg vials: 1 vial every 4 weeks
	Vasoactive intestinal peptide-secreting tumor, associated diarrhea	Up to 30 mg every 4 weeks	• 10 mg, 20 mg, and 30 mg vials: 1 vial every 4 weeks
Pasireotide diaspartate (Signifor)	Cushing's Syndrome	Up to 0.9 mg twice daily	• 0.3 mg, 0.6 mg, and 0.9 mg ampules: 60 every 30 days
Pasireotide pamoate (Signifor LAR)	Acromegaly	Up to 60 mg every 4 weeks	• 10 mg, 20 mg, 30 mg, 40 mg, and 60 mg vials: 1 vial every 4 weeks
	Cushing's Syndrome	Up to 40 mg every 4 weeks	• 10 mg, 20 mg, 30 mg, and 40 mg vials: 1 vial every 4 weeks

Coding:

HCPCS Code	Description
J1930	Injection, lanreotide, 1 mg
J1932	Injection, lanreotide, (Cipla), 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
J2502	Injection, pasireotide long acting, 1 mg

Background:

Acromegaly is an endocrine disorder characterized by excessive growth hormone (GH) and insulin-like growth factor 1 (IGF1) levels, typically caused by tumor secretion. The excess in GH and IGF1 levels lead to complications which include, but are not limited to, soft tissue overgrowth, cardiovascular disease and metabolic dysfunction.[1] Treatment management includes normalizing GH and IGF-1 levels. First-line medical management consists of transsphenoidal surgery to remove the tumors. For patients who are not surgical candidates or continue to experience the disease after surgery, pharmacologic treatment is typically considered. First-line pharmacologic therapy includes octreotide or lanreotide. Pasireotide is recommended as second-line.[1]

Carcinoid syndrome is a condition typically caused by well-differentiated neuroendocrine tumors. "These tumors secrete biogenic amines, particularly serotonin, which lead to hallmark symptoms that include flushing and diarrhea."[2] Treatment of carcinoid syndrome primarily consists of somatostatin analogs.[2]

Cushing's syndrome is typically caused by long-term exposure to excessive glucocorticoids (exogenous Cushing's syndrome) from steroid medications or tumors (endogenous Cushing's syndrome). Exogenous Cushing's syndrome is treated by tapering steroid medications gradually. Standard treatment for endogenous Cushing's syndrome is surgical removal. When surgery is not an option or fails, adrenal steroidogenesis inhibitors can be used. This includes, but is not limited to, pasireotide, ketoconazole, metyrapone, osiolodristat cabergoline, mitotane, and levoketoconazole.[4, 5]

Chemotherapy-induced diarrhea is an adverse effect from certain chemotherapy agents that may cause inflammation of mucous membranes in the gastrointestinal tract. First-line treatment options include loperamide. Second-line management options include octreotide and opium tincture.[6,7]

Vasoactive intestinal peptide-secreting tumor (VIPoma) associated diarrhea is a main symptom for patients with a VIPoma. It is characterized by watery stools, rich in electrolytes, which may result in hypokalemia and metabolic acidosis.[8] Treatment includes correction of fluids and electrolytes and the use of somatostatin analogs (e.g. octreotide) may be used to reduce stool volume and frequency.[8,9]

The safety and efficacy of Somatuline Depot for the treatment of gastroenteropancreatic neuroendocrine tumors (GEPNETs) was established in a randomized, placebo-controlled trial in 204 patients with well or moderately differentiated, metastatic or locally advanced, GEPNETs. Patients in the Somatuline Depot group had a significant difference in progression-free survival compared to placebo at 22 months.[10]

References

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13. Sandostatin LAR Depot [Prescribing Information]. East Hanover, NJ. Novartis. July 2024.
14. Signifor [Prescribing Information]. Recordati Rare Diseases. Bridgewater, NJ. July 2024.
15. Signifor LAR [Prescribing Information]. Recordati Rare Diseases. Bridgewater, NJ. July 2024.

History

Approved Date	Effective Date	Version	Action and Summary of Changes
08/13/2025	02/01/2026	30.17.00-1	New policy created