

Endocrine and Metabolic Agents : Somatostatic Agents

Medical policy no. 30.17.00-1

Effective Date: TBD

Related medical policies:

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 Apple Health Preferred Drug List (AHPDL), please visit: <https://www.hca.wa.gov/assets/billers-and-providers/apple-health-preferred-drug-list.xlsx>

Medical necessity

Drug	Medical Necessity
Lanreotide acetate (Somatuline Depot) Octreotide acetate (Mycapssa) Octreotide acetate (Sandostatin) Octreotide acetate Mi-Spheres (Sandostatin LAR Depot) Pasireotide diaspertate (Signifor) Pasireotide pamoate (Signifor LAR)	<p>Endocrine and Metabolic Agents : Somatostatic Agents may be considered medically necessary in patients who meet the criteria described in the clinical policy below.</p> <ul style="list-style-type: none"> 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 Non-Clinical Policy No 0001 (NC-001). <p>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.</p>

Clinical policy:

Clinical Criteria	
Acromegaly Lanreotide acetate (Somatuline Depot) Octreotide acetate (Mycapssa) Octreotide acetate (Sandostatin) Octreotide acetate Mi-Spheres (Sandostatin LAR Depot) Pasireotide pamoate (Signifor LAR)	<p>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:</p> <ol style="list-style-type: none"> 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 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 <ol style="list-style-type: none"> a. Rational is provided why the patient is unable to use injectable octreotide. <p>If ALL criteria are met, the request will be authorized for 6 months.</p>
Criteria (Reauthorization)	
	<p>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:</p> <ol style="list-style-type: none"> 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., normalization of serum IGF-1, normalization of growth hormone, adenoma shrinkage]. <p>If ALL criteria are met, the request will be authorized for 12 months.</p>
Carcinoid Syndrome Lanreotide acetate (Somatuline Depot) Octreotide acetate (Sandostatin) Octreotide acetate Mi-Spheres (Sandostatin LAR Depot)	<p>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:</p> <ol style="list-style-type: none"> 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). <p>If ALL criteria are met, the request will be authorized for 6 months.</p>

	<p>Criteria (Reauthorization)</p> <p>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:</p> <ol style="list-style-type: none"> 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.]. <p>If ALL criteria are met, the request will be authorized for 12 months.</p>
<p>Cushing's Syndrome Pasireotide diaspertate (Signifor) Pasireotide pamoate (Signifor LAR)</p>	<p>Pasireotide diaspertate (Signifor) or pasireotide pamoate (Signifor LAR) may be approved when all the following documented criteria are met:</p> <ol style="list-style-type: none"> 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 provides attestation that the patient has failed or is not a candidate for surgery to treat Cushing's Syndrome. <p>If ALL criteria are met, the request will be authorized for 6 months.</p> <p>Criteria (Reauthorization)</p> <p>Pasireotide diaspertate (Signifor) or pasireotide pamoate (Signifor LAR) may be approved when all the following documented criteria are met:</p> <ol style="list-style-type: none"> 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]. <p>If ALL criteria are met, the request will be authorized for 12 months.</p>
<p>Diarrhea, chemotherapy-induced, severe or persistent Octreotide acetate (Sandostatin)</p>	<p>Octreotide acetate (Sandostatin) may be approved when all the following documented criteria are met:</p> <ol style="list-style-type: none"> 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. <p>If ALL criteria are met, the request will be authorized for 6 months.</p>

	<p>Criteria (Reauthorization)</p> <p>Octreotide acetate (Sandostatin) may be approved when all the following documented criteria are met:</p> <ol style="list-style-type: none"> 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]. <p>If ALL criteria are met, the request will be authorized for 12 months.</p>
<p>Vasoactive intestinal peptide-secreting tumor, associated diarrhea Octreotide acetate (Sandostatin) Octreotide acetate Mi-Spheres (Sandostatin LAR Depot)</p>	<p>Octreotide acetate (Sandostatin) or octreotide acetate Mi-Spheres (Sandostatin LAR Depot) may be approved when all the following documented criteria are met:</p> <ol style="list-style-type: none"> 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. <p>If ALL criteria are met, the request will be authorized for 6 months.</p>
	<p>Criteria (Reauthorization)</p> <p>Octreotide acetate (Sandostatin) or octreotide acetate Mi-Spheres (Sandostatin LAR Depot) may be approved when all the following documented criteria are met:</p> <ol style="list-style-type: none"> 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]. <p>If ALL criteria are met, the request will be authorized for 12 months.</p>
<p>Well-differentiated neuroendocrine tumor, gastroenteropancreatic Lanreotide acetate (Somatuline Depot)</p>	<p>Lanreotide acetate (Somatuline Depot) may be approved when all the following documented criteria are met:</p> <ol style="list-style-type: none"> 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. <p>If ALL criteria are met, the request will be authorized for 6 months.</p>

	Criteria (Reauthorization)
	<p>Lanreotide acetate (Somatuline Depot) may be approved when all the following documented criteria are met:</p> <ol style="list-style-type: none"> 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]. <p>If ALL criteria are met, the request will be authorized for 6 months.</p>

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	<ul style="list-style-type: none"> 60 mg, 90 mg, and 120 mg syringes: 1 syringe every 4 weeks
	Carcinoid Syndrome	120 mg every 4 weeks	<ul style="list-style-type: none"> 120 mg syringes: 1 syringe every 4 weeks
	Well-differentiated neuroendocrine tumor, gastroenteropancreatic	120 mg every 4 weeks	<ul style="list-style-type: none"> 120 mg syringes: 1 syringe every 4 weeks
Octreotide acetate (Mycapssa)	Acromegaly	Up to 80 mg daily	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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 microspheres (Sandostatin LAR Depot)	Acromegaly	Up to 40 mg every 4 weeks	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 10 mg, 20 mg, and 30 mg vials: 1 vial every 4 weeks
Pasireotide diaspertate (Signifor)	Cushing's Syndrome	Up to 0.9 mg twice daily	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 10 mg, 20 mg, 30 mg, and 40 mg vials: 1 vial every 4 weeks

Coding:

HCPSC 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
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, osilodristat 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

1. Melmed S, Bronstein MD, Chanson P, et al. A Consensus Statement on acromegaly therapeutic outcomes. *Nat Rev Endocrinol*. 2018;14(9):552-561.
2. Menon G, Pandit S, Annamaraju P, et al. Carcinoid Syndrome. [Updated 2025 Feb 18]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK448096/>
3. George J, Ramage J, White B, Srirajaskanthan R. The role of serotonin inhibition within the treatment of carcinoid syndrome. *Endocr Oncol*. 2023;3(1):e220077.
4. Nieman LK, Biller BM, Findling JW, et al. Treatment of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*.
5. Cushing's syndrome. Gadelha, Mônica et al. *The Lancet*, Volume 402, Issue 10418, 2237 – 2252.
6. Stein A, Voigt W, Jordan K. Chemotherapy-induced diarrhea: pathophysiology, frequency and guideline-based management. *Ther Adv Med Oncol*. 2010 Jan;2(1):51-63.
7. Elad S, Cheng KKF, Lalla RV, et al, Mucositis Guidelines Leadership Group of the Multinational Association of Supportive Care in Cancer and International Society of Oral Oncology (MASCC/ISOO). MASCC/ISOO clinical practice guidelines for the management of mucositis secondary to cancer therapy. *Cancer*. 2020 Oct 1;126(19):4423-4431.

8. de Herder WW, Hofland J. Vasoactive Intestinal Peptide-Secreting Tumor (VIPoma) [Updated 2023 Apr 5]. In: Feingold KR, Ahmed SF, Anawalt B, et al., editors. Endotext [Internet]. South Dartmouth (MA): MDText.com, Inc.; 2000.
9. Schiller LR, Pardi DS, Sellin JH. Chronic Diarrhea: Diagnosis and Management. *Clin Gastroenterol Hepatol*. 2017;15(2):182-193.
10. Somatuline Depot [Prescribing Information]. Signes, France: Ipsen Pharma Biotech. July 2024.
11. Mycapssa [Prescribing Information]. Scotland, UK. Chiesi. July 2024.
12. Sandostatin [Prescribing Information]. East Hanover, NJ. Novartis. July 2024.
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
MM/DD/YYYY	MM/DD/YYYY	30.17.00-1	Pending Approval (draft/unpublished version) - New policy created

Endocrine and Metabolic: Somatostatic Agents

Please provide the information below, please print your answer, attach supporting documentation, sign, date, and return to our office as soon as possible to expedite this request. **Without this information, we may deny the request in seven (7) working days.**

Date of request:	Reference #:	MAS:	
Patient	Date of birth	ProviderOne ID	
Pharmacy name	Pharmacy NPI	Telephone number	Fax number
Prescriber	Prescriber NPI	Telephone number	Fax number
Medication and strength		Directions for use	Qty/Days supply

1. Is this request for a continuation of existing therapy? ☐ Yes ☐ No

If yes, is there documentation demonstrating disease stability or a positive clinical response (e.g., normalization of serum IGF-1, normalization of growth hormone, adenoma shrinkage, improvement of flushing, improvement of diarrhea, reduction in tumor volume, decrease in urine free cortisol)?

☐ Yes ☐ No

2. Is this prescribed by, or in consultation with, any of the following? Check all that apply:

☐ Endocrinologist

☐ Oncologist

☐ Other. Specify: _____

3. Will this medication be used in combination with another somatostatic agent (e.g. lanreotide, octreotide)?

☐ Yes ☐ No

4. Indicate patient's diagnosis and answer the associated questions as indicated:

☐ Acromegaly

Is provider able to attest that the patient is not a candidate for surgery to treat Acromegaly?

☐ Yes ☐ No

Is the request for Mycapssa? ☐ Yes ☐ No

If yes, provide documentation of demonstrated response and tolerance to treatment with octreotide or lanreotide.

☐ Carcinoid syndrome

Is patient experiencing symptoms related to carcinoid syndrome (e.g., diarrhea, flushing)?

☐ Yes ☐ No

☐ Cushing's Syndrome

Is provider able to attest that the patient has not failed or is not a candidate for surgery to treat Cushing's Syndrome?

☐ Yes ☐ No

☐ Severe or persistent diarrhea due to chemotherapy

Does the patient have a history of failure, contraindication, or intolerance to loperamide?

☐ Yes ☐ No

☐ Vasoactive intestinal peptide-secreting tumor (VIPoma)

Is the request for the management of diarrhea due to VIPoma?

☐ Yes ☐ No

☐ Gastroenteropancreatic neuroendocrine tumor

Has patient been diagnosed with gastroenteropancreatic neuroendocrine tumor that is unresectable, well- or moderately-differentiated, locally advanced or metastatic? ☐ Yes ☐ No

☐ Other. Specify: _____

CHART NOTES ARE REQUIRED WITH THIS REQUEST

Prescriber signature

Prescriber specialty

Date