Washington State Health Care Authority

# Endocrine and Metabolic Agents : Somatostatic Agents

## Medical policy no. 30.17.00-1 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 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)<br>Octreotide acetate (Mycapssa)<br>Octreotide acetate (Sandostatin)<br>Octreotide acetate Mi-Spheres (Sandostatin LAR Depot)<br>Pasireotide diaspartate (Signifor)<br>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.<br><br>• 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).<br><br>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 | |
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| **Acromegaly**<br>Lanreotide acetate (Somatuline Depot)<br>Octreotide acetate (Mycapssa)<br>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:<br>1. Patient is 18 years of age or older, **AND**<br>2. Prescribed by, or in consultation with, an endocrinologist; **AND** |

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

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

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

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| | 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].<br><br>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 |
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| **Lanreotide acetate (Somatuline Depot)** | Acromegaly | Initial: 90 mg every 4 weeks for 3 months<br>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<br>Maintenance: Up to 500 mcg 3 times daily | • 50 mcg ampules/syringes/vials: 90 every 30 days<br>• 100 mcg ampules/syringes/vials: 90 every 30 days<br>• 500 mcg ampules/syringes/vials: 90 every 30 days<br>• 1000 mcg/5 mL vials: 45 vials every 30 days<br>• 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<br>• 100 mcg ampules/syringes/vials: 90 every 30 days<br>• 500 mcg ampules/syringes/vials: 90 every 30 days<br>• 1000 mcg/5 mL vials: 45 vials every 30 days<br>• 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<br>• 100 mcg ampules/syringes/vials: 90 every 30 days<br>• 500 mcg ampules/syringes/vials: 90 every 30 days |

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| | | | • 1000 mcg/5 mL vials: 45 vials every 30 days<br>• 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<br>• 100 mcg ampules/syringes/vials: 90 every 30 days<br>• 500 mcg ampules/syringes/vials: 90 every 30 days<br>• 1000 mcg/5 mL vials: 23 vials every 30 days<br>• 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<br>• 20 mg vials: 2 vials every 4 weeks<br>• 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 |
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| 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 |