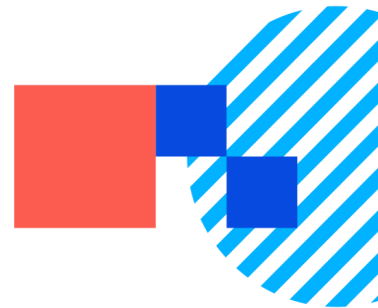




Somatostatin Analogs Prior Authorization

Drug List A

Drug(s) Applied:	Octreotide acetate (short-acting), lanreotide acetate, Somatuline Depot, octreotide acetate LAR (long-acting)
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Criteria:

Drug(s) Applied will be approved when the requested medication is being used for a compendia-supported indication and all of the following criteria are met:

I. Initial Therapy Criteria

A. **Acromegaly** as indicated by chart notes within past 120 days

1. ONE of the following:

- Patient had an inadequate response to surgical resection or pituitary radiation therapy as indicated by pre-treatment growth hormone and serum insulin-like growth factor-1 (IGF-1) levels that are above the reference ranges
- Patient is not a candidate for surgical resection or pituitary radiation therapy and has pre-treatment growth hormone and IGF-1 levels that are above the reference ranges **and**

2. ONE of the following:

- If patient's post-surgical or post-radiation therapy IGF-1 level is <2.5 times the upper limit of normal (ULN) of the reference range, then patient has tried and had an inadequate response to a dopamine agonist (e.g., cabergoline) after an adequate trial (e.g., ≥12 weeks), or patient has a contraindication or severe intolerance to dopamine agonists
- If patient is not a candidate for surgical resection or pituitary radiation therapy and has a pre-treatment IGF-1 level <2.5 times the upper limit of normal (ULN) of the reference range, then patient has tried and had an inadequate response to a dopamine agonist (e.g., cabergoline) after an adequate trial (e.g., ≥12 weeks), or patient has a contraindication or severe intolerance to dopamine agonists **and**

- Prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinology)

Approval Duration: 3 months

B. **Metastatic carcinoid tumors** as indicated by chart notes within past 120 days



1. Patient has flushing and/or diarrhea associated with metastatic carcinoid tumors **and**
2. Patient's age is within FDA labeling for the requested indication or there is support for using the requested agent for the patient's age for the requested indication **and**
3. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., oncology)

Approval Duration: 6 months

C. Vasoactive Intestinal Peptide secreting tumors (VIPomas) as indicated by chart notes within past 120 days

1. Patient has profuse watery diarrhea associated with VIP secreting tumors **and**
2. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., oncology)

Approval Duration: 6 months

D. Gastroenteropancreatic neuroendocrine tumors (GEP-NETs) as indicated by chart notes within past 120 days

1. Tumors are well differentiated or moderately differentiated **and**
2. Tumors are unresectable locally advanced or patient has metastatic disease **and**
3. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., oncology)

Approval Duration: 6 months

E. Another compendia-supported indication as indicated by chart notes within past 120 days

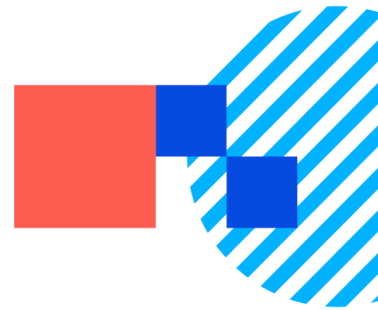
1. Requested drug is FDA-approved or NCCN-supported with category 1 or 2A for the requested indication **and**
2. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., oncology)

Approval Duration: 6 months

II. Continued Therapy Criteria

A. Acromegaly as indicated by chart notes within past 180 days

1. ONE of the following:
 - a) If patient has been treated with the requested agent for <3 months, patient meets the initial therapy criteria above
 - b) If patient has been treated with the requested agent for ≥3 months, ONE



of the following:

- (a) Patient had an inadequate response to surgical resection or pituitary radiation therapy as indicated by pre-treatment growth hormone and serum insulin-like growth factor-1 (IGF-1) levels that are above the reference ranges
- (b) Patient is not a candidate for surgical resection or pituitary radiation therapy and has pre-treatment growth hormone and IGF-1 levels that are above the reference ranges **and**
- 2. Documented clinical benefit since starting the requested agent (i.g, normalized IGF-1 and/or growth hormone levels) **and**
- 3. Prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinology)

Approval Duration: 12 months

B. All oncology indications as indicated by chart notes within past 180 days

- 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization process or meets the initial therapy criteria above **and**
- 2. Documented clinical benefit since starting the requested agent (i.e., decrease in symptom severity/frequency, reduction in tumor size) **and**
- 3. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., oncology)

Approval Duration: 12 months

References:

- 1. Sandostatin LAR prescribing information. Novartis. December 2025.
- 2. Somatuline Depot prescribing information. Ipsen Biopharmaceuticals, Inc. October 2024.
- 3. Octreotide prescribing information. Mylan Institutional LLC. July 2024.
- 4. Lanreotide prescribing information. Cipla USA Inc. February 2025.
- 5. Mehmed S. et al. Consensus on acromegaly therapeutic outcomes: an update. Nature Reviews Endocrinology. August 2025.
- 6. Fleseriu M. et al. A Pituitary Society update to acromegaly management guidelines. Pituitary. Oct 2020.
- 7. Ogedegbe OJ, Cheema AY, Khan MA, et al. A Comprehensive Review of Four Clinical Practice Guidelines of Acromegaly. Cureus. 2022;14(9):e28722. Published 2022 Sep 3. doi:10.7759/cureus.28722
- 8. Daniel CP, Wagner MJ, Borne GE, et al. Acromegaly: Pathophysiological Considerations and Treatment Options Including the Evolving Role of Oral Somatostatin Analogs. Pathophysiology. 2023;30(3):377-388. doi:10.3390/pathophysiology30030029.

Policy Owned by: Curative PBM team