Pharmacy Drug Policy & Procedure

Policy Name:	Sandostatin (octreotide) and Sandostatin LAR (octreotide)	Policy #:	1741P

Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of octreotide acetate, Sandostatin, and Sandostatin LAR.

Statement of the Policy

Health Alliance Medical Plans will approve the use of Sandostatin and octreotide acetate under the specialty pharmacy benefit or Sandostatin LAR under the specialty medical benefit when the following criteria have been met.

Criteria

1. Coverage Criteria for the Treatment of Acromegaly

1.1 Prescribed by an endocrinologist (hormone doctor)

1.2 Diagnosis of acromegaly

1.3 High Insulin-like Growth Factor (IGF-1) levels for age (lab values are required)

1.4 Documented inadequate response to surgery or radiotherapy or clinical reason why the patient has not had surgery or radiotherapy

1.5 If request is a new start for Sandostatin LAR, documented 2-week treatment with Sandostatin injection which was effective and tolerated

2. Coverage Criteria for the Treatment of High-Grade Poorly-Differentiated Neuroendocrine Tumor (NET)

2.1 Prescribed by an specialist knowledgeable in the treatment of NETs

2.2 Sandostatin/Sandostatin LAR will be used in addition cancer therapy

3. Coverage Criteria for the Treatment of Well Differentiated (Carcinoid) NET

3.1 Prescribed by an specialist knowledgeable in the treatment of NETs

3.2 Diagnosis of one of the following:

- Metastatic disease for which surgery cannot be performed
- Cancer releasing tumors
- Significant tumor burden
- Abnormal lung tumors despite cancer treatment
- Lung NET with positive octreotide scan

4. Coverage Criteria for the Treatment of Pancreatic NET

4.1 Prescribed by an specialist knowledgeable in the treatment of NETs

4.2 Diagnosis of one of the following:

- Insulinoma (pancreas tumors)
- Gastrinoma (intestinal tumors)

- VIPoma (endocrine tumors)
- Pituitary adenoma (pituitary tumors)

5. Coverage Criteria for the Treatment of Acute Chemotherapy-Related Diarrhea

5.1 Prescribed by an oncologist (cancer doctor) or hematologist (blood disorder doctor)

5.2 Documentation that the member is currently receiving a chemotherapy regimen

5.3 Documented trial and failure, intolerance, or contraindication to loperamide (generic for Imodium) or diphenoxylate-atropine (generic for Lomotil)

6. Coverage Criteria for the Treatment of Diarrhea Associated with Graft-Versus-Host Disease (GVHD)

6.1 Prescribed by an oncologist (cancer doctor) or hematologist (blood disorder doctor)

6.2 Diagnosis of steroid-refractory gut GVHD

6.3 Documented trial and failure, intolerance, or contraindication to loperamide (generic for Imodium) or diphenoxylate-atropine (generic for Lomotil)

7. Approval Period

7.1 12 months

CPT Codes	
96372	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); subcutaneous or intramuscular

HCPCS Codes	
J2353	Injection, octreotide, depot form for intramuscular injection, 1 mg
J2354	Injection, octreotide, non-depot form for subcutaneous or intravenous injection, 25 mcg

References

1. Sandostatin LAR Depot (octreotide injection suspension) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2024.
2. Sandostatin (octreotide injection solution) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; November 2023.
3. American Association of Clinical Endocrinologists Acromegaly Guidelines Task Force. Medical guidelines for clinical practice for the diagnosis and treatment of acromegaly – 2011 update. Endocr Pract. 2011;17(suppl 4):1–44.
4. Benson AB 3rd, Ajani JA, Catalano RB, et al. Recommended guidelines for the treatment of cancer treatment-induced diarrhea, J Clin Oncol. 2004 Jul 15;22(14):2918-26.
5. Klimstra DS. Pathology, classification, and grading of neuroendocrine tumors arising in the digestive system. In: UpToDate, Goldberg RM (Ed), UpToDate, Waltham, MA. (Accessed on February 18, 2016.)
6. Melmed S, Colao A, Barkan A, et al. Acromegaly Consensus Group. Guidelines for acromegaly management: an update. Clin Endocrinol Metab. 2009;94(5):1509–17.
7. Melmed S. Acromegaly pathogenesis and treatment. J Clin Invest. 2009;119(11):3189–202.
8. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org. Accessed February 18, 2016.
9. National Institute of Diabetes and Digestive and Kidney Disease. Acromegaly. Bethesda, MD: National Institutes of Health; 2008. http://endocrine.niddk.nih.gov/pubs/acro/acro.htm. Accessed November 7, 2011.

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.