Drug Policy:

Somatostatin Analogs

POLICY NUMBER UM ONC_1042	SUBJECT Somatostatin Analogs: Sandostatin™/ Sandostatin LAR Depot™ (octreotide) and Somatuline Depot™ (lanreotide)		DEPT/PROGRAM UM Dept	PAGE 1 of 4
DATES COMMITTEE REVIEWED 01/12/11, 03/08/12, 11/13/13, 03/05/15, 03/27/15, 04/11/16, 02/06/17, 12/28/17, 01/10/18, 02/06/19, 12/11/19, 02/12/20, 11/11/20, 02/10/21, 11/15/21, 01/12/22, 05/11/22, 01/11/23, 01/10/24, 01/08/25	**APPROVAL DATE** January 08, 2025	**EFFECTIVE DATE** January 31, 2025	**COMMITTEE APPROVAL DATES** 01/12/11, 03/08/12, 11/13/13, 03/05/15, 03/27/15, 04/11/16, 02/06/17, 12/28/17, 01/10/18, 02/06/19, 12/11/19, 02/12/20, 11/11/20, 02/10/21, 11/15/21, 01/12/22, 05/11/22, 01/11/23, 01/10/24, 01/08/25	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Evolent Specialty Services Clinical Guideline Review Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid	

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses clinical guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. A list of codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this clinical guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their plan customer service representative for specific coverage information.

I. PURPOSE

To define and describe the accepted indications for Somatostatin analogs usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided:

1. The member has not experienced disease progression on the requested medication AND
2. The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization AND
3. Additional medication(s) are not being added to the continuation request.

B. Meningiomas

1. Sandostatin (octreotide LAR Depot/IV/SQ) or Somatuline Depot (lanreotide) may be used for recurrent or progressive disease, when radiation and/or surgery are not feasible and the tumor/disease is positive on an Octreoscan (or similar imaging confirming that the tumor is somatostatin receptor positive).

C. NETS: Neuro Endocrine Tumors

1. Sandostatin (octreotide LAR Depot/IV/SQ) or Somatuline Depot (lanreotide) is being used in members with metastatic/unresectable neuroendocrine tumors originating in the gastrointestinal tract/pancreas/lung/adrenal glands/other organs (except small cell lung cancer) as a single agent or in combination with other therapies.
    a. As symptom control in members with carcinoid syndrome or symptoms suggestive of carcinoid syndrome, e.g., diarrhea, flushing AND/OR
    b. For tumor/disease control.

D. Thymomas and Thymic Carcinomas

1. The member has unresectable/metastatic thymoma or thymic carcinomas AND
2. The tumor/disease is positive on an Octreoscan (or similar imaging confirming that the tumor is somatostatin receptor positive) AND
3. Sandostatin (octreotide LAR Depot/IV/SQ) or Somatuline Depot (lanreotide) is being used for locally advanced/metastatic disease with or without prednisone.

III. EXCLUSION CRITERIA

A. Dosing exceeds single dose limit of 60 mg Sandostatin LAR Depot (octreotide) or 500 mcg of Sandostatin IV/SQ (octreotide),

B. Dosing exceeds single dose limit Somatuline Depot (lanreotide) 120 mg.

C. Investigational use of Somatostatin analogs with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
    1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
    2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
    3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definition of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.

4. Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

IV. CODING INFORMATION

HCPCS Code	Description
J2353	Injection, octreotide, depot form for intramuscular injection, 1 mg
J2354	Injection, octreotide, non-depot form for subcutaneous or intravenous injection, 25 mcg
J3490	octreotide acetate
J8499	octreotide, oral
J1930	Injection, lanreotide, 1 mg
J1932	Injection, lanreotide, (cipla), 1 mg
J3490	lanreotide
C9399	lanreotide

V. MEDICATION MANAGEMENT

A. Please refer to the FDA label/package insert for details regarding these topics.

VI. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VII. ATTACHMENTS

A. None

VIII. REFERENCES

A. Oncotarget, Merola et al Antiproliferative effect of somatostatin analogs in advanced gastro-entero-pancreatic neuroendocrine tumors: a systematic review and meta-analysis.

B. Loehrer PJ Sr, et al. Eastern Cooperative Oncology Group Phase II Trial. Octreotide alone or with prednisone in patients with advanced thymoma and thymic carcinoma: an Eastern Cooperative Oncology Group Phase II Trial. J Clin Oncol. 2004 Jan 15;22(2):293-9.

C. Hrachova et al. Front Neurol. 2020; 11: 373. Published online 2020 May 6. doi: 10.3389/fneur.2020.00373

D. Sandostatin prescribing information. Novartis Pharmaceuticals Corporation. East Hanover, New Jersey 2021.

E. Sandostatin LAR depot prescribing information. Novartis Pharmaceuticals Corporation. East Hanover, New Jersey 2021.

F. Somatuline (lanreotide) prescribing information. Ipsen Biopharmaceuticals, Inc. 2019.

G. Clinical Pharmacology Elsevier Gold Standard 2025.

H. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2025.

I. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2025.

J. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2025.

K. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.

L. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.

M. Current and Resolved Drug Shortages and Discontinuations Reported to the FDA: http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.