Drug Policy:

Somatostatin Analogs

POLICY NUMBER UM ONC_1042	**SUBJECT** Somatostatin Analog: Sandostatin™/ Sandostatin LAR Depot™ (octreotide) and Somatuline Depot™ (lanreotide)	**DEPT/PROGRAM** UM Dept	**PAGE 1 of 3**
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	**APPROVAL DATE** January 10, 2024	**EFFECTIVE DATE** January 26, 2024	**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
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee	
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**	**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid	

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. MEDICATION MANAGEMENT

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

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. 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 2023.

H. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2023.

I. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2023.

J. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2023.

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.

N. NCQA UM 2023 Standards and Elements.