



POLICY NUMBER UM ONC_1042	SUBJECT Somatostatin Analog: Sandostatin™ (octreotide) and Somatuline™ (lanreotide)		DEPT/PROGRAM UM Dept	PAGE 1 OF 2
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	APPROVAL DATE February 12, 2020	EFFECTIVE DATE March 01, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 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	
PRIMARY BUSINESS OWNER: UM APPROVED BY: Dr. Andrew Hertler		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
URAC STANDARDS		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.

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century 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

1. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

- a. When health plan Medicaid coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the Preferred Drug Guidelines OR
- b. When health plan Exchange coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the Preferred Drug Guidelines OR
- c. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the Preferred Drug Guidelines shall follow NCH L1 Pathways when applicable, otherwise shall follow NCH drug policies: <http://pathways.newcenturyhealth.com> AND
- d. Continuation requests of previously approved non-preferred medication are not subject to this provision AND
- e. When available, generic alternatives are preferred over brand-name drugs.

2. Unless contraindications, intolerance, or failure exist, the PREFERRED Somatostatin analog for all indications is Sandostatin (octreotide) over Somatuline (lanreotide).

3. Neuroendocrine and Adrenal Tumors

- a. Somatostatin Analog is being used in member with any of the following:
 - i. Management of unresectable locoregional disease and/or distant metastases for the following:
 - a) As symptom control in members with carcinoid syndrome **AND/OR**



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b) For tumor control.

4. **Thymomas and Thymic Carcinomas**

- a. The member has thymomas or thymic carcinomas and Sandostatin SQ or LAR depot (octreotide) is being used as second line therapy for locally advanced with or without prednisone.

5. **Meningiomas**

- a. Sandostatin SQ or LAR depot (octreotide) is being used for recurrent or progressive disease, when radiation is not possible, and octreotide scan positive.

III. **EXCLUSION CRITERIA**

1. Dosing exceeds single dose limit of 40 mg Sandostatin LAR depot (octreotide) or 500 mcg of Sandostatin SQ (Octreotide).
2. Dosing exceeds single dose limit Somatuline (lanreotide) 120 mg.
3. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

III. **MEDICATION MANAGEMENT**

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

IV. **APPROVAL AUTHORITY**

1. Review – UM Department
2. Final Approval – UM Committee

V. **ATTACHMENTS**

None

VII. **REFERENCES**

1. Sandostatin prescribing information. Novartis Pharmaceuticals Corporation. East Hanover, New Jersey. 2019.
2. Sandostatin LAR depot prescribing information. Novartis Pharmaceuticals Corporation. East Hanover, New Jersey. 2019.
3. Somatuline (lanreotide) prescribing information. Ipsen Biopharmaceuticals, Inc. 2019.
4. Clinical Pharmacology Elsevier Gold Standard. 2020.
5. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
6. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
7. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.