

# Drug Policy:

## Somatostatin Analog:

### Sandostatin™/Bynfezia Pen™/ Sandostatin LAR Depot™ (octreotide) and Somatuline Depot™ (lanreotide)

<b>POLICY NUMBER</b> UM ONC_1042	<b>SUBJECT</b> Somatostatin Analog: Sandostatin™/ Bynfezia™/ Sandostatin LAR Depot™ (octreotide) and Somatuline™ (lanreotide)		<b>DEPT/PROGRAM</b> UM Dept	<b>PAGE 1 OF 3</b>
<b>DATES COMMITTEE REVIEWED</b> 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	<b>APPROVAL DATE</b> February 10, 2021	<b>EFFECTIVE DATE</b> February 26, 2021	<b>COMMITTEE APPROVAL DATES</b> (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, 11/11/20, 02/10/21	
<b>PRIMARY BUSINESS OWNER:</b> UM		<b>COMMITTEE/BOARD APPROVAL</b> Utilization Management Committee		
<b>URAC STANDARDS</b> HUM 1	<b>NCQA STANDARDS</b> UM 2		<b>ADDITIONAL AREAS OF IMPACT</b>	
<b>CMS REQUIREMENTS</b>	<b>STATE/FEDERAL REQUIREMENTS</b>		<b>APPLICABLE LINES OF BUSINESS</b> 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 Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH 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. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. 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](#)
2. 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](#)
3. 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 **AND**
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision **AND**
5. When available, generic alternatives are preferred over brand-name drugs.
6. **NOTE:** The preferred Somastatin Analog is Sandostatin IV/SC or LAR Depot (octreotide) over Bynfezia Pen (octreotide) or Somatuline Depot (lanreotide). Somatuline Depot (lanreotide) may be used in members with contraindication/intolerance to OR failure of Sandostatin IV/SC or LAR Depot (octreotide).

### B. NETS: Neuro Endocrine Tumors

1. Sandostatin IV/SQ or LAR Depot (octreotide) 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.

### C. 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 IV/SQ or LAR Depot (octreotide) is being used for locally advanced/metastatic disease with or without prednisone.

### D. Meningiomas

1. Sandostatin IV/SQ or LAR Depot (octreotide) is being used for recurrent or progressive disease, when radiation is not possible, and the octreotide scan is positive.

## III. EXCLUSION CRITERIA

- A. Dosing exceeds single dose limit of 60 mg Sandostatin LAR Depot (octreotide), 500 mcg of Sandostatin IV/SQ (octreotide), or 600 mcg of Bynfezia Pen (octreotide).
- B. Dosing exceeds single dose limit Somatuline Depot (lanreotide) 120 mg.
- C. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.



## 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, et al J Clin Oncol 22:293-299, 2004.
- C. Sandostatin prescribing information. Novartis Pharmaceuticals Corporation. East Hanover, New Jersey 2020.
- D. Sandostatin LAR depot prescribing information. Novartis Pharmaceuticals Corporation. East Hanover, New Jersey 2020.
- E. Somatuline (lanreotide) prescribing information. Ipsen Biopharmaceuticals, Inc. 2019.
- F. Bynfezia Pen prescribing information. Sun Pharmaceutical Industries, Inc. 2020.
- G. Clinical Pharmacology Elsevier Gold Standard 2021.
- H. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2021.
- I. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2021.
- J. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2021.