SmartPA Criteria Proposal

Drug/Drug Class:	Somatostatin Analogs PDL Edit
First Implementation Date:	April 1, 2021
Proposed Date:	December 16, 2021
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☒Existing Criteria ☐Revision of Existing Criteria ☐New Criteria

Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

Why Issue Selected: Somatostatin, also known as growth inhibiting hormone, is a cyclic peptide hormone that is produced to the highest extent within the gastrointestinal tract, islets of Langerhans within the pancreas, and the nervous system. Somatostatin functions to inhibit the secretion of various hormones including growth hormone, prolactin, vasoactive intestinal peptide, glucagon, thyroid-stimulating hormone, and insulin. By binding to and activating five distinct G-protein coupled receptors (GPCR), somatostatin decreases intracellular cyclic AMP and calcium and increases outward potassium currents, the net effect of which is a decrease in hormone secretion within the target tissue.

Somatostatin analogs which mimic the action of endogenous somatostatin have been available since the 1980's and are now used to treat a variety of conditions. Octreotide, has shown to have a higher affinity than natural somatostatin for the sst_2 GPCR subtype which predominates in neuroendocrine tumors; this led to the approval of products such as Sandostatin®, Sandostatin® LAR Depot, and Somatuline® Depot for use in adult patients with diarrhea or flushing associated with vasoactive intestinal peptide tumors and gastroenteropancreatic neuroendocrine tumors. Additional indications include the treatment of carcinoid syndrome as well as acromegaly, a disorder resulting from excess growth hormone production.

Somatuline® Depot (lanreotide), approved in 2007, was developed to create a longer acting, pre-filled product and formulated to allow for easier administration as a deep subcutaneous injection. Most recently, in June 2020, Mycapssa® became the first FDA approved oral somatostatin analog. Whereas all other products are required to be administered by a healthcare provider via intravenous infusion, subcutaneous or intramuscular injection, Mycapssa delayed-release oral capsules allow for patient self-administration. Prior to initiating any long-acting somatostatin products, patients must have responded to and tolerated prior treatment with octreotide (or lanreotide in the case of Mycapssa) which requires three times daily injections for a minimum of two weeks.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:	Preferred Agents	Non-Preferred Agents
	• Octreotide (gen Sandostatin®) • Sandostatin® LAR Depot	• Bynfezia Pen™ • Mycapssa® • Sandostatin® • Somatuline® Depot

Type of Criteria: ☐ **Increased risk of ADE** ☒ **Preferred Drug List**
☒ **Appropriate Indications** ☐ **Clinical Edit**

Data Sources: ☐ **Only Administrative Databases** ☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Somatostatin Analogs
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Documented compliance on current therapy regimen **OR**
- Participant aged 18 years or older **AND**
- Failure to achieve desired therapeutic outcomes with trial of 2 preferred agents
  - Documented trial period of preferred agents **OR**
  - Documented ADE/ADR to preferred agents
- For Somatuline Depot: Clinical Consultant Review required

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met
- Claim exceeds maximum dosing limitations for the following:

Drug Description	Generic Equivalent	Max Dosing Limitation
MYCAPSSA 20 MG DR CAPSULE	OCTREOTIDE	4 capsules per day

Required Documentation

Laboratory Results: ☐ Progress Notes: ☐
MedWatch Form: ☐ Other: ☐

Disposition of Edit

Denial: Exception Code “0160” (Preferred Drug List)
Rule Type: PDL

Default Approval Period

1 year

References

- Evidence-Based Medicine and Fiscal Analysis: “Somatostatin Analogs – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; November 2021.
- Evidence-Based Medicine Analysis: “Somatostatin Agents”, UMKC-DIC; September 2021.
- Wolin, Edward M. The Expanding Role of Somatostatin Analogs in the Management of Neuroendocrine Tumors. Gastrointestinal Cancer Research. 2012; 5(5):161-168.
- O’toole, Timothy J, Sharma, Sandeep. Physiology, Somatostatin. StatPearls Publishing. 2020. Available from: https://www.ncbi.nlm.nih.gov/books/NBK538327/.
- Mycapssa® (octreotide) [package insert]. Scotland, UK: MW Encap Ltd; June 2020.
- Sandostatin® LAR Depot (octreotide acetate) [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2021.
- Somatuline® Depot (lanreotide) [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc; June 2019.