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 sst2 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:

<table>
<thead>
<tr>
<th>Preferred Agents</th>
<th>Non-Preferred Agents</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Octreotide (gen Sandostatin®)</td>
<td>• Bynfezia Pen™</td>
</tr>
<tr>
<td>• Sandostatin® LAR Depot</td>
<td>• Lanreotide</td>
</tr>
<tr>
<td>• Sandostatin®</td>
<td>• Mycapssa®</td>
</tr>
<tr>
<td>• Sandostatin® Depot</td>
<td>• Somatuline® Depot</td>
</tr>
</tbody>
</table>

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

• Participant aged 18 years or older AND
• Failure to achieve desired therapeutic outcomes with trial of 2 preferred agents
  o Documented trial period of preferred agents OR
  o Documented ADE/ADR to preferred agents OR
• Documented compliance on current therapy regimen
• 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:

<table>
<thead>
<tr>
<th>Drug Description</th>
<th>Generic Equivalent</th>
<th>Max Dosing Limitation</th>
</tr>
</thead>
<tbody>
<tr>
<td>MYCAPSSA 20 MG DR CAPSULE</td>
<td>OCTREOTIDE</td>
<td>4 capsules per day</td>
</tr>
</tbody>
</table>

Required Documentation

Laboratory Results:  
MedWatch Form:  
Progress Notes:  
Other:  

Disposition of Edit

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

Default Approval Period

1 year
References