| Field Name          | Field Description   |
|---------------------|---|
| Prior Authorization | Somatostatin Analogs and Growth Hormone Receptor Antagonists  |
| Group Description   | gogo  |
| Drugs               | Octreotide (Sandostatin)  |
| 8                   | Sandostatin LAR (octreotide)  |
|                     | Lanreotide 120 mg/0.5 mL  |
|                     | <b>Lanreotide</b> (Somatuline Depot) (lanreotide) 60 mg/0.2 mL, 90 mg/0.3   |
|                     | mL, 120 mg/0.5mL  |
|                     | Mycapssa (octreotide)   |
|                     | Signifor (pasireotide)  |
|                     | Signifor LAR (pasireotide)  |
|                     | Somavert (pegvisomant)  |
| Covered Uses        | Medically accepted indications are defined using the following  |
|                     | sources: the Food and Drug Administration (FDA) Drug Package Insert   |
|                     | (PPI).  |
|                     |   |
|                     | ** Non-FDA approved (i.e. off-label) uses; refer to the "Oncology   |
| P 1 1 G 1           | Drugs" policy for off-label oncology uses**   |
| Exclusion Criteria  | N/A   |
| Required Medical    | See "Other Criteria"  |
| Information         | D DDA 1 1 1 1 1   |
| Age Restrictions    | Per FDA approved package insert   |
| Prescriber          | Prescriber must be a specialist with appropriate expertise in treating the  |
| Restrictions        | condition in question (such as an endocrinologist,  |
|                     | neurologist/neurosurgeon, oncologist, etc.). Consultation with appropriate specialist for the condition in question is also acceptable. |
| Coverage Duration   | If all of the criteria are met, the initial request will be approved for 6  |
| Coverage Duration   | months. For continuation of therapy, the request will be approved for   |
|                     | 12 months.  |
| Other Criteria      | **Drug is being requested through the member's medical  |
|                     | benefit**   |
|                     | ***************************************   |
|                     | <u>Initial Authorization</u>  |
|                     | For all FDA approved indications (including FDA-approved oncology   |
|                     | related uses)   |
|                     | Medication requested is for an FDA approved indication and  |
|                     | dose  |
|                     | <ul> <li>If the provider is requesting therapy with more than one</li> </ul>  |
|                     | somatostatin analog or a somatostatin analog and a growth   |
|                     | hormone receptor antagonist, then documentation must be   |
|                     | submitted as to why patient is unable to be treated with  |
|                     | monotherapy, or a medical reason was provided why   |
|                     | monotherapy is not appropriate.   |
|                     |   |
|                     | For Acromegaly  |

- Patient has had an inadequate response to, or medical reason why, surgical treatment cannot be used.
- If the patient mild disease (e.g. mild signs and symptoms of growth hormone excess, modest elevations in IGF-1) there is a documented trial of a dopamine agonist (e.g. bromocriptine mesylate, cabergoline) at a therapeutically appropriate dose or a documented medical reason why a dopamine agonist cannot be used

### • Additionally for Mycapssa:

- o Patient has showed clinical response to and tolerates treatment with octreotide or lanreotide therapy
- Clinical justification is provided as to why patient cannot continue use of injectable somatostatin analog therapy

## • Additionally for Somavert:

 Patient has had an inadequate response to therapy with a somatostatin analog, or has a documented medical reason why a somatostatin analog cannot be used

# • Additionally for Signifor LAR:

Patient has had an inadequate response to therapy with either lanreotide (Somatuline Depot) or octreotide (Sandostain, Sandostatin LAR), or has a documented medical reason why these somatostatin analogs cannot be used.

# Revision/Review Date 4/202**54**

### For Cushing's Disease (pasireotide products only)

• Patient must have had inadequate response, or medical reason why surgical treatment cannot be used

#### Reauthorization

- Medication requested is for an FDA approved indication and dose
- Documentation has been provided that demonstrates a clinical benefit (e.g. improvement in laboratory values, improvement or stabilization of clinical signs/symptoms, etc.)

Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.