

| <u>Field Name</u> | <u>Field Description</u> |
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| <u>Prior Authorization Group Description</u> | <u>Somatostatin Analogs and Growth Hormone Receptor Antagonists</u> |
| <u>Drugs</u> | <u>Octreotide (Sandostatin)</u> <u>Sandostatin LAR (octreotide)</u> <u>Lanreotide 120 mg/0.5 mL</u> <u>Somatuline Depot (lanreotide) 60 mg/0.2 mL, 90 mg/0.3 mL, 120 mg/0.5mL</u> <u>Mycapssa (octreotide)</u> <u>Signifor (pasireotide)</u> <u>Signifor LAR (pasireotide)</u> <u>Somavert (pegvisomant)</u> |
| <u>Covered Uses</u> | <u>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA) Drug Package Insert (PPI).</u> <u>** Non-FDA approved (i.e. off-label) uses; refer to the “Oncology Drugs” policy for off-label oncology uses**</u> |
| <u>Exclusion Criteria</u> | <u>N/A</u> |
| <u>Required Medical Information</u> | <u>See “Other Criteria”</u> |
| <u>Age Restrictions</u> | <u>Per FDA approved package insert</u> |
| <u>Prescriber Restrictions</u> | <u>Prescriber must be a specialist with appropriate expertise in treating the condition in question (such as an endocrinologist, neurologist/neurosurgeon, oncologist, etc.). Consultation with appropriate specialist for the condition in question is also acceptable.</u> |
| <u>Coverage Duration</u> | <u>If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.</u> |
| <u>Other Criteria</u> | <u>**Drug is being requested through the member’s medical benefit**</u> <u>Initial Authorization</u> <u>For all FDA approved indications (including FDA-approved oncology related uses)</u> <ul style="list-style-type: none"> <u>Medication requested is for an FDA approved indication and dose</u> <u>If the provider is requesting therapy with more than one 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</u> |

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| <p><u>Revision/Review</u> <u>Date 4/2024</u></p> | <p><u>monotherapy, or a medical reason was provided why monotherapy is not appropriate.</u></p> <p><u>For Acromegaly</u></p> <ul style="list-style-type: none"> • <u>Patient has had an inadequate response to, or medical reason why, surgical treatment cannot be used.</u> • <u>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</u> • <u>Additionally for Mycapssa:</u> <ul style="list-style-type: none"> ○ <u>Patient has showed clinical response to and tolerates treatment with octreotide or lanreotide therapy</u> ○ <u>Clinical justification is provided as to why patient cannot continue use of injectable somatostatin analog therapy</u> • <u>Additionally for Somavert:</u> <ul style="list-style-type: none"> ○ <u>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</u> • <u>Additionally for Signifor LAR:</u> <ul style="list-style-type: none"> ○ <u>Patient has had an inadequate response to therapy with either lanreotide (Somatuline Depot) or octreotide (Sandostatin, Sandostatin LAR), or has a documented medical reason why these somatostatin analogs cannot be used.</u> <p><u>For Cushing's Disease (pasireotide products only)</u></p> <ul style="list-style-type: none"> • <u>Patient must have had inadequate response, or medical reason why surgical treatment cannot be used</u> <p><u>Reauthorization</u></p> <ul style="list-style-type: none"> • <u>Medication requested is for an FDA approved indication and dose</u> • <u>Documentation has been provided that demonstrates a clinical benefit (e.g. improvement in laboratory values, improvement or stabilization of clinical signs/symptoms, etc.)</u> <p><u>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</u></p> |
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