AETNA BETTER HEALTH®

Prior Authorization guideline for Somatostatin Analogs

Drugs Covered

- Octreotide - preferred
- Sandostatin LAR \( ^{*} \) (octreotide) - preferred
- Signifor LAR \( ^{*} \) (pasireotide)
- Signifor \( ^{*} \) (pasireotide)
- Somatuline Depot \( ^{*} \) (lanreotide) - preferred

Authorization guidelines

General Criteria for ALL Indications:

A. Sandostatin LAR:
   1. Baseline A1c or fasting glucose, thyroid-stimulating hormone (TSH), and electrocardiography (EKG)
   2. Positive response to octreotide immediate release injection for at least 2 weeks

B. Somatuline Depot:
   1. Baseline A1c or fasting glucose
   2. Trial and failure of Sandostatin LAR, or intolerance to octreotide or Sandostatin LAR except for the indication of Gastroenteropancreatic Neuroendocrine Tumors (GEP-NET)

C. Signifor and Signifor LAR:
   1. Baseline A1c, fasting plasma glucose, EKG, potassium, magnesium, TSH, and liver function tests (LFTs)
   2. Trial and failure of Sandostatin LAR, or intolerance to octreotide or Sandostatin LAR

Additional criteria for use in Acromegaly (octreotide, Sandostatin LAR, Somatuline Depot, Signifor LAR):

- Patient meets general criteria above for requested medication
- Patient is 18 years of age or older
- Prescribed by, or in consultation with an endocrinologist
- Patient has persistent disease following pituitary surgery, or surgical resection is not an option as evidenced by one of the following:
  1. Majority of tumor cannot be resected
  2. Patient is a poor surgical candidate based on comorbidities
  3. Patient prefers medical treatment over surgery, or refuses surgery
- Baseline insulin-like growth factor 1 (IGF-1) is >2x upper limit of normal (ULN) for age OR IGF-1 remains elevated despite a 6 month trial of maximally tolerated dose of cabergoline (unless patient cannot tolerate cabergoline or has a contraindication)

Additional criteria for use for Carcinoid tumor or VIPomas (octreotide, Sandostatin LAR, Somatuline Depot):

Revised April 2014
A. Patient meets general criteria above for requested medication  
B. Patient is 18 years of age or older  
C. Prescribed by, or in consultation with oncologist or endocrinologist  

Criteria for use for Cushing’s syndrome (Signifor):  
A. Patient must be 18 years of age or older  
B. Patient has persistent disease after pituitary surgery, or surgery is not an option  
C. Trial and failure of, or intolerance/contraindication to cabergoline  
D. Baseline A1c, fasting plasma glucose, EKG, potassium, magnesium, TSH and LFT’s  
E. NOTE: Patient does not need a trial of octreotide for approval  

Additional criteria for off-label use† for Hepatorenal syndrome (octreotide):  
A. Patient must be 18 years of age or older  
B. Prescribed by hepatologist or nephrologist  
C. Must be used in combination with midodrine and albumin  

Additional criteria for Gastroenteropancreatic neuroendocrine tumor (GEP-NET) (octreotide, Sandostatin LAR, Somatuline Depot):  
A. Patient meets general criteria above for requested medication  
B. Patient must be 18 years of age or older  
C. Prescribed by or in consultation with oncologist or endocrinologist  
D. Patient has persistent disease after surgical resection, or is not a candidate for surgery  
E. Somatuline Depot requests do not require prior trial with octreotide and/or Sandostatin LAR as it is FDA approved for this indication  

Octreotide may be reviewed for medical necessity and may be approved for treatment of the following off-label† indications:  
A. Chemotherapy induced diarrhea in pediatrics, when prescribed by or in consultation with oncologist  
B. Dumping Syndrome in adults ≥18 years of age  
C. Enterocutaneous fistula in adults ≥18 years of age  
D. Hyperthyroidism due to thyrotropinoma in adults ≥18 years of age  
E. Short bowel syndrome (associated diarrhea) in adults ≥18 years of age  
F. Portal hypertension and/or upper GI bleed related to variceal bleeding in patients with esophageal varices in adults ≥18 years of age  

†Off-label indications included based on peer-reviewed clinical studies  

Additional Information:  
These agents are NOT covered for members with the following criteria:  
• Use not approved by the FDA; AND  
• The use is unapproved and not supported by the literature or evidence as an accepted off-label use.  

Quantity Limits:  
• Octreotide: Maximum dose is 1500mcg/day  
• Sandostatin LAR: Maximum dose is 40mg every 4 weeks  

Revised: 9/2016  
Previous PARP Approval: 12/2016  
Current PARP Approval: 6/2018
o 10mg and 30mg vials: 1 vial per 28 days
o 20mg vials: 2 vials per 28 days
• Signifor: 2 vials per day
• Signifor LAR: 1 vial per 28 days
• Somatuline Depot: 1 syringe per 28 days

Approval Duration:
Initial Approval: - 6 months

Renewal:
• Acromegaly and Cushing’s: Indefinite
• Carcinoid and VIPomas: Indefinite
• All other indications: 6 months
• Clinical documentation required:
  o Response to therapy and A1c or fasting glucose
  o For Acromegaly: Decreased or normalized IGF-1 levels
  o For Carcinoid and VIPomas: Symptom improvement
  o For Cushing’s: Decreased or normalized cortisol levels
  For Signifor: LFT’s

Medically Necessary — A service or benefit is Medically Necessary if it is compensable under the MA Program and if it meets any one of the following standards:

• The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.

• The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.

• The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

Determination of Medical Necessity for covered care and services, whether made on a Prior Authorization, Concurrent Review, Retrospective Review, or exception basis, must be documented in writing.

The determination is based on medical information provided by the Member, the Member’s family/caretaker and the Primary Care Practitioner, as well as any other Providers, programs, agencies that have evaluated the Member.

All such determinations must be made by qualified and trained Health Care Providers. A Health Care Provider who makes such determinations of Medical Necessity is not considered to be providing a health care service under this Agreement.
References:
2. Sandostatin (octreotide acetate) [package insert]. West Hartford, CT: Novartis Pharmaceuticals Corporation; Revised March 2012.