Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Long-Acting Somatostatin Analogue: Sandostatin® LAR Depot, Somatuline® Depot, Signifor® LAR***
DEPARTMENT: **Clinical Pharmacy Services – Utilization Management**
ORIGINAL DATE: ***January 2010 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *August 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Sandostatin® LAR Depot (octreotide acetate), Somatuline® Depot (lanreotide acetate), and Signifor® LAR (pasireotide).

- Sandostatin® LAR Depot (octreotide acetate) is indicated for patients whom initial treatment with Sandostatin injection has been shown to be effective and tolerated.
- Sandostatin® LAR Depot (octreotide acetate) is indicated for long-term treatment of:
  - Patients with acromegaly who have had an inadequate response to surgery or radiotherapy or for whom these treatments are not appropriate
  - Severe diarrhea and flushing episodes associated with metastatic carcinoid tumors
  - Profuse watery diarrhea associated with vasoactive intestinal peptide secreting tumors
- Somatuline® Depot (lanreotide acetate) is indicated for:
  - the long-term treatment of patients with acromegaly who have had an inadequate response to surgery or radiotherapy, or for whom surgery or radiotherapy is not an option
  - The treatment of patients with unresectable, well, or moderately differentiated locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival

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  - The treatment of carcinoid syndrome, to reduce the frequency of short-acting somatostatin analog rescue therapy.
- Signifor® LAR (pasireotide) is indicated for the treatment of patients with acromegaly who have had an inadequate response to surgery and/or for whom surgery is not an option.
- Signifor® LAR (pasireotide) is indicated for the treatment of patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative

DEFINITIONS

Acromegaly – a disease characterized by hypersecretion of growth hormone (GH) which is most commonly caused by a pituitary somatroph adenoma. Increased circulating levels of GH stimulate increased hepatic production of insulin-like growth factor-1 (IGF-1). Excess IGF-1 causes increased growth of bones and soft-tissues while excess GH can cause co-morbid conditions such as diabetes mellitus, hypertension, and increased cardiovascular risk. Lower circulating GH levels can cause a reversal in the co-morbid diseases and a decrease in IGF-1.

Metastatic carcinoid tumors – tumors of the gastrointestinal tract formed from the endocrine (argentaffin) cells of the mucosal lining of a variety of organs including the stomach and intestine that have metastasized, or spread, to nearby muscle tissue and lymph nodes, or distant organs, such as the liver, and bones. Symptoms of these tumors include facial flushing, diarrhea, abdominal pain, asthma, rash, heart disease, and intestinal bleeding.

Vasoactive intestinal peptide tumors (VIPomas) – rare cancers in which tumor cells arise from certain hormone-producing cells called islet cells most often located in the pancreas. VIPomas produce excessive amounts of hormones, particularly vasoactive intestinal peptide, which disrupts water transport in the intestines causing the symptom of watery diarrhea, which is the most prominent symptom.

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drugs, Sandostatin® LAR Depot (octreotide acetate), Somatuline® Depot (lanreotide

acetate), and Signifor® LAR (pasireotide), are subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

I. PLAN DESIGN SUMMARY

Requests for Sandostatin® LAR and Signifor® LAR are subject to the preferred medical drug list program. This program applies to the acromegaly products specified in this policy. Coverage for a targeted product is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with the targeted product.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Acromegaly Products

	Product(s)
Preferred	• Somatuline® Depot (lanreotide) • Somavert® (pegvisomant)
Non-Preferred	• Sandostatin® LAR (octreotide acetate for injectable suspension) • Signifor® LAR (pasireotide)

Requests for a non-preferred drug must meet one of the following exception criteria in addition to clinical criteria:

II. EXCEPTION *CRITERIA (Use for Sandostatin® LAR/Signifor® LAR Requests Only)*

This program applies to members requesting treatment for an indication that is FDA-approved for both of the preferred products.

Coverage for a non-preferred product is provided when ANY of the following criteria is met:

A. Member is currently receiving treatment with the non-preferred product through health insurance, excluding when the non-preferred product is obtained as samples or via manufacturer's patient assistance programs.
B. Member has had a documented inadequate response or intolerable adverse event to ONE of the preferred products.

III. CLINICAL CRITERIA (*Use for ALL Drug Requests*)

Must meet all of the clinical criteria listed under the respective diagnosis:

1. Acromegaly

- Must be prescribed by or in consultation with an endocrinologist
- Must be age 18 years or older
- Must have a confirmed diagnosis of acromegaly to include both of the following baseline (pre-treatment) labs:
    - Elevated serum IGF-1 level for patient's gender and age range. Laboratory reference range must be provided
    - Elevated growth hormone (GH) level defined as a GH level ≥1ng/mL during oral glucose tolerance test (OGTT)
- Must have an inadequate response to surgery or radiation therapy, or documentation that these therapies are not appropriate
- For Signifor LAR only:
    - Must provide recent (within 6 months) hemoglobin A1c
    - For members with a hemoglobin A1c value greater than 8%, documentation that anti-diabetic therapy has been optimized must be provided

2. Cushing's Disease (applies to Signifor LAR only)

- Must be prescribed by or in consultation with an endocrinologist
- Must be age 18 years or older
- Must have an inadequate response to surgery or documentation that surgery is not appropriate
- Must provide recent (within 6 months) hemoglobin A1c
- For members with a hemoglobin A1c value greater than 8%, documentation that anti-diabetic therapy has been optimized must be provided

3. **Severe diarrhea and flushing episodes associated with metastatic carcinoid tumors (applies to Sandostatin LAR only)**
   - Must be prescribed by or in consultation with a hematologist, oncologist, endocrinologist, or palliative care specialist
   - Must have a diagnosis of metastatic carcinoid tumor with associated severe diarrhea and flushing episodes

4. **Carcinoid syndrome (applies to Somatuline Depot only)**
   - Must be prescribed by or in consultation with a hematologist, oncologist, endocrinologist, or palliative care specialist
   - Must have a diagnosis of carcinoid syndrome

5. **Profuse watery diarrhea associated with vasoactive intestinal peptide secreting tumors (applies to Sandostatin LAR only)**
   - Must be prescribed by or in consultation with a hematologist, oncologist, endocrinologist, or palliative care specialist
   - Member must have a diagnosis of vasoactive intestinal peptide secreting tumors with associated profuse watery diarrhea

6. **Gastricenteropancreatic neuroendocrine tumors (GEP-NETs) (applies to Somatuline Depot only)**
   - Must be prescribed by or in consultation with a hematologist, oncologist, endocrinologist, or palliative care specialist
   - Must have diagnosis of unresectable, well- or moderately-differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEPNETs)

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	• Acromegaly and Cushing's: up to 3 months • Severe diarrhea and flushing episodes associated with metastatic carcinoid tumors (Sandostatin LAR only): up to 2 months • Profuse watery diarrhea associated with vasoactive intestinal peptide secreting tumors (Sandostatin LAR only): up to 2 months • Gastricenteropancreatic neuroendocrine tumors (Somatuline Depot only): up to 6 months
Reauthorization	Up to 1 year
Quantity Level Limit	
Sandostatin LAR Depot	10mg and 30mg: 1 kit per 28 days 20mg: 2 kits per 28 days
Signifor LAR	1 kit per 28 days
Somatuline Depot	1 syringe per 28 days

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Sandostatin LAR Depot (octreotide acetate for injectable suspension) [Product Information]. Novartis. East Hanover, NJ. July 2016.
2. Somatuline Depot (lanreotide acetate) [Product Information]. Ipsen Pharma Biotech. Signes, France. December 2014.
3. American Association of Clinical Endocrinologists Acromegaly Task Force. AACE Acromegaly Guidelines. Endocr Pract 2011;17(suppl 4)
4. Melmed S, Colao A, Molitch M, et al. Guidelines for Acromegaly Management: An Update. J Clin Endocrinol Metab. 2009;94:1509-1517.
5. Signifor LAR [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2014.
6. Colao A, Bronstein MD, Freda P, et al. Pasireotide versus octreotide in acromegaly: a head-to-head superiority study. J Clin Endocrinol Metab 2014;99:791-799

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/16, 02/17, 02/18*
Indication Update	*07/17, 01/18, 8/18*
Preferred Product Update (effective 4/1/18)	*02/18*