UTILIZATION MANAGEMENT POLICY

POLICY: Somatostatin Analogs for Acromegaly

APPROVAL DATE: 09/11/2019

DRUGS AFFECTED:

- Sandostatin® LAR Depot (octreotide acetate for injectable suspension – Novartis)
- Signifor® LAR (pasireotide for injectable suspension – Novartis)
- Somatuline® Depot (lanreotide injection – Ipsen)

OVERVIEW

Sandostatin LAR Depot, Signifor LAR, and Somatuline Depot are all long-acting somatostatin analogs indicated for the treatment of acromegaly in patients who have had an inadequate response to surgery, and/or radiotherapy, or in patients for whom surgery and/or radiotherapy is not an option.[1-3] Of note, Sandostatin LAR Depot is only indicated in patients who tolerated and had an effective response to initial treatment with octreotide subcutaneous (SC) injection. Sandostatin LAR Depot and Somatuline Depot have additional indications in patients with certain types and/or symptoms of neuroendocrine tumors (NETs).[1,3] All three of the long-acting somatostatin analogs bind to somatostatin receptors (SSTRs) and have pharmacologic properties mimicking those of the natural hormone somatostatin.[1-3] However, the affinity with which each binds to the various subtypes of SSTRs varies. This policy involves the use of these products. For more information on criteria within a Prior Authorization (PA) by specific condition refer to the following policies.[4-6]

- *Sandostatin LAR Depot PA Policy*
- *Signifor LAR PA Policy*
- *Somatuline Depot PA Policy*

GUIDELINES

The Endocrine Society Clinical Practice Guidelines for Acromegaly (2014) recommend transsphenoidal surgery as the primary therapy in most patients; repeat surgery may be considered in patients with residual intrasellar disease after initial surgery.[7] Although routine preoperative medical therapy is not recommended, patients with severe pharyngeal thickness and sleep apnea or high-output heart failure may receive therapy with a somatostatin analog preoperatively to reduce surgical risk from severe comorbidities. A somatostatin analog may be used as primary therapy in patients who cannot be cured by surgery; have extensive cavernous sinus invasion; do not have chiasmal compression; or are poor surgical candidates. For patients with persistent disease after surgery, Somatuline Depot and Sandostatin LAR Depot are equally effective and neither is preferred over the other by the guidelines. The guidelines have not been updated since the FDA-approval of Signifor LAR, but do note the enhanced binding of this agent to somatostatin receptors and the data supporting its ability to normalize IGF-1 levels.

POLICY STATEMENT

This PSM program requires the patient to meet Standard Prior Authorization (PA) criteria and requires the patient to try the preferred product (Somatuline Depot), when clinically appropriate, prior to the approval of a non-preferred product (Sandostatin LAR Depot and Signifor LAR). Patients meeting the PA criteria for a non-preferred product who have not tried a preferred product will be offered a review for the preferred product. All approvals for preferred and non-preferred products are provided for 1 year in duration.

Automation: None

Preferred Product: Somatuline Depot
Non-Preferred Product: Sandostatin LAR Depot, Signifor LAR

RECOMMENDED EXCEPTION CRITERIA

Trade Name	Exception
Sandostatin LAR Depot	**1. Acromegaly:** **A)** Approve if the patient meets the following criteria (i and ii): **i.** Patient meets theStandard *Somatostatin Analogs – Sandostatin LAR Depot PA Policy* criteria; AND **ii.** Patient has tried Somatuline Depot. **B)** For patients who have not tried the preferred product (Somatuline Depot) for acromegaly, offer to review using the Standard *Somatostatin Analogs – Somatuline Depot PA Policy*. **2. Other Conditions:** Approve if the patient meets the Standard *Somatostatin Analogs – Sandostatin LAR Depot PA Policy* criteria.
Signifor LAR	**1. Acromegaly:** **A)** Approve if the patient meets the following criteria (i and ii): **i.** Patient meets the Standard *Somatostatin Analogs – Signifor LAR PA policy* criteria; AND **ii.** Patient has tried Somatuline Depot. **B)** For patients who have not tried the preferred product (Somatuline Depot) for acromegaly, offer to review using the Standard *Somatostatin Analogs – Somatuline Depot PA Policy*. **2. Other Conditions:** Approve if the patient meets the Standard *Somatostatin Analogs – Signifor LAR PA Policy* criteria.

REFERENCES

1. Sandostatin® LAR Depot for injectable suspension [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2019.
2. Signifor® LAR for injectable suspension [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2019.
3. Somatuline® Depot injection [prescribing information]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; April 2019.
4. Sandostatin LAR Depot prior authorization policy for preferred specialty management.
5. Signifor LAR prior authorization policy for preferred specialty management.
6. Somatuline Depot prior authorization policy for preferred specialty management.
7. Katznelson L, Laws ER Jr, Melmed S, et al; Endocrine Society. Acromegaly: an endocrine society clinical practice guideline. *J Clin Endocrinol Metab.* 2014;99:3933-3951.