

<b>Reference number</b>
2096-A

## SPECIALTY GUIDELINE MANAGEMENT

### SIGNIFOR LAR (pasireotide injectable suspension)

#### POLICY

##### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

##### FDA-Approved Indications

- A. Treatment of patients with acromegaly who have had an inadequate response to surgery and/or for whom surgery is not an option
- B. Treatment of patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative

All other indications are considered experimental/investigational and not medically necessary.

##### II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

- A. For acromegaly:
  - 1. For initial approval: Laboratory report indicating high pretreatment insulin-like growth factor-1 (IGF-1) level and chart notes indicating an inadequate or partial response to surgery or a clinical reason for not having surgery.
  - 2. For continuation: Laboratory report indicating normal current IGF-1 levels or chart notes indicating that the member's IGF-1 level has decreased or normalized since initiation of therapy.
- B. Cushing's disease:
  - 1. For initial requests, pretreatment cortisol level as measured by one of the following tests:
    - a. Urinary free cortisol (UFC) level
    - b. Late-night salivary cortisol
    - c. 1 mg overnight dexamethasone suppression test (DST)
    - d. Longer, low dose DST (2 mg per day for 48 hours)
  - 2. For continuation of therapy (if applicable), laboratory report indicating current cortisol level has decreased from baseline as measured by one of the following tests:
    - a. Urinary free cortisol (UFC) level
    - b. Late-night salivary cortisol
    - c. 1 mg overnight dexamethasone suppression test (DST)
    - d. Longer, low dose DST (2 mg per day for 48 hours)

##### III. CRITERIA FOR INITIAL APPROVAL

###### A. Acromegaly

Authorization of 12 months may be granted for the treatment of acromegaly when all of the following criteria are met:

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1. Member has a high pretreatment IGF-1 level for age and/or gender based on the laboratory reference range.
2. Member had an inadequate or partial response to surgery OR there is a clinical reason why the member has not had surgery.

**B. Cushing's disease**

Authorization of 12 months may be granted for the treatment of Cushing's disease when the member has had surgery that was not curative OR the member is not a candidate for surgery.

**IV. CONTINUATION OF THERAPY**

**A. Acromegaly**

Authorization of 12 months may be granted for continuation of therapy for acromegaly when the member's IGF-1 level has decreased or normalized since initiation of therapy.

**B. Cushing's disease**

Authorization of 12 months for continuation of therapy may be granted for members that meet one of the following criteria:

1. Lower cortisol levels since the start of therapy per one of the following tests:
  - a. Urinary free cortisol (UFC)
  - b. Late-night salivary cortisol
  - c. 1 mg overnight dexamethasone suppression test (DST)
  - d. Longer, low dose DST (2 mg per day for 48 hours)
2. Improvement in signs and symptoms of the disease

**V. REFERENCES**

1. Signifor LAR [package insert]. Bridgewater, NJ: Recordati Rare Diseases Inc.; August 2023.
2. Katznelson L, Laws ER Jr, Melmed S, et al. Acromegaly: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2014;99:3933-3951.
3. American Association of Clinical Endocrinologists Acromegaly Guidelines Task Force. Medical guidelines for clinical practice for the diagnosis and treatment of acromegaly – 2011 update. *Endocr Pract.* 2011;17(suppl 4):1-44.
4. Gadelha MR, Bronstein MD, Brue T, et al. Pasireotide versus continued treatment with octreotide or lanreotide in patients with inadequately controlled acromegaly (PAOLA): a randomized, phase 3 trial. *Lancet Diabetes Endocrinol.* 2014;2:875-84.
5. 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.
6. Nieman LK, Biller BM, Findling JW, et al. Treatment of Cushing's syndrome: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab.* 2015;100(8):2807-31.
7. Fleseriu M, Auchus R, Bancos I, et al. Consensus on Diagnosis and Management of Cushing's Disease: A Guideline Update. *Lancet Diabetes Endocrinol.* 2021; 9: 847-875.