CVS Caremark®

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| Reference number(s) |
| 2096-A |

# Specialty Guideline Management Signifor LAR

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Signifor LAR | pasireotide |

## 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 Indications1

* Treatment of patients with acromegaly who have had an inadequate response to surgery and/or for whom surgery is not an option.
* 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.

## Documentation

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

### For Acromegaly:

* 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.
* 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.

### Cushing’s Disease:

* For initial requests, pretreatment cortisol level as measured by one of the following tests:
  + Urinary free cortisol (UFC) level
  + Late-night salivary cortisol
  + 1 mg overnight dexamethasone suppression test (DST)
  + Longer, low dose DST (2 mg per day for 48 hours)
* For continuation of therapy (if applicable), laboratory report indicating current cortisol level has decreased from baseline as measured by one of the following tests:
  + Urinary free cortisol (UFC) level
  + Late-night salivary cortisol
  + 1 mg overnight dexamethasone suppression test (DST)
  + Longer, low dose DST (2 mg per day for 48 hours)

## Coverage Criteria

### Acromegaly1-5

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

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

### Cushing’s Disease1,7

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.

## Continuation of Therapy

### Acromegaly1-5

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.

### Cushing’s Disease1,7

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

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

## References

1. Signifor LAR [package insert]. Bridgewater, NJ: Recordati Rare Diseases Inc.; July 2024.
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.