

## Signifor® LAR (pasireotide) Injectable Suspension

When requesting Signifor® LAR (pasireotide) injectable suspension, the individual requiring treatment must be diagnosed with one of the following FDA-approved indications or the approved off-label compendial use and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

### FDA-Approved Indications

#### Acromegaly

Signifor LAR is indicated for the treatment of patients with acromegaly who have had an inadequate response to surgery and/or whom surgery is not an option.

#### Cushing's Disease

Signifor LAR is indicated for the treatment of patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative.

### Approved Off-label Compendial Use

- Endogenous Cushing's Syndrome

### Coverage Guidelines

#### Acromegaly

The individual must meet **all** following criteria for approval:

- Meets one of the following:
  - Had an inadequate response to surgery and/or radiotherapy; OR
  - Is not an appropriate candidate for surgery and/or radiotherapy; OR
  - Is experiencing negative effects due to tumor size (e.g., optic nerve compression);
- Has/had a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender for the reporting laboratory;
- Signifor LAR is prescribed by or in consultation with an endocrinologist.

#### Cushing's Disease

The individual must meet both the following criteria for initial approval:

- Is not a candidate for surgery or surgery has not been curative;
- Signifor LAR is prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of Cushing's disease.

The individual must meet the following criterion for reauthorization:

- Is responding to the therapy (e.g., decrease in the mean urinary free cortisol level).

## Endogenous Cushing's Syndrome

The individual must meet all of the following criteria for approval:

- Is 18 years of age or older;
- Meets one of the following:
  - o Is not a candidate for surgery or surgery has not been curative; OR
  - o Is awaiting for surgery; OR
  - o Is awaiting therapeutic response after radiotherapy;
- Signifor LAR is prescribed by or in consultation with an endocrinologist or a physician who specialized in the treatment of Cushing's syndrome.

**Approval Duration:** 4 months for Cushing's disease (initial only); 12 months for others

## Dosing Recommendations

### Acromegaly

The recommended initial dose is 40 mg administered by intramuscular injection once every 4 weeks. The dose may be increased to a maximum of 60 mg for patients who have not normalized growth hormone (GH) and/or age and sex adjusted insulin-like growth factor-1 (IGF-1) levels after 3 months of treatment.

### Cushing's Disease/Cushing's Syndrome

The recommended initial dose is 10 mg administered by intramuscular injection once every 4 weeks. The dose may be increased to a maximum of 40 mg for patients who have not normalized 24-hour urinary free cortisol after 4 months of treatment.

## References

1. Signifor® LAR injectable suspension[prescribing information]. Lebanon, NJ: Recordati Rare Diseases; July 2024.
2. Sharma ST, Nieman LK, Feelders RA. Cushing's syndrome: epidemiology and developments in disease management. *Clin Epidemiol*. 2015;7:281–293.
3. Tritos NA, Biller BM. Advances in medical therapies for Cushing's syndrome. *Discov Med*. 2012;13(69):171-179.
4. Biller BMK, Grossman AB, Stewart PM, et al. Treatment of adrenocorticotropin-dependent Cushing's syndrome: A consensus statement. *J Clin Endocrinol Metab*. 2008;93:2454-2462.
5. Nieman LK, Biller BM, Findling JW. Treatment of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2015;100(8):2807-2831.
6. 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(12):847-875.