

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 an 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.