

Signifor® LAR (pasireotide) Injection

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

FDA-Approved Indications

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

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 Uses

- Cushing's Disease/Syndrome- Patients Awaiting Surgery
- Cushing's Disease- Patients Awaiting Therapeutic Response After Radiotherapy

Coverage Guidelines

Acromegaly

The individual must meet following criteria for approval:

- 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) **AND**
- 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 **AND**
- Signifor LAR is prescribed by or in consultation with an endocrinologist

Cushing's disease

- Is awaiting for surgery or therapeutic response after radiotherapy **OR**
- For an initial therapy, the individual is not a candidate for surgery or surgery has not been curative **OR**
- For a continuation therapy, the individual is responding to the therapy (e.g., decrease in the mean urinary free cortisol level) **AND**
- Signifor LAR is prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of Cushing's disease/syndrome

Approval Duration: 4 months (for Cushing' disease awaiting for surgery or therapeutic response after radiotherapy)

Approval Duration: 12 months (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 60mg for patients who have not normalized growth hormone and/or age and sex adjusted insulin-like growth factor-1 (IGF-1) levels after 3 months of treatment with Signifor LAR at 40mg

Cushing's disease

- The recommended initial dose is 10 mg administered by intramuscular injection once every 4 weeks
- After 4 months of treatment with the initial dose, the dose may be increased up to a maximum dose of 40 mg once every 28 days in patients who have not normalized 24-hour urinary free cortisol.

References

1. Signifor® LAR injectable suspension [prescribing information]. Lebanon, NJ: Recordati Rare Diseases; March 2020.
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.