

Signifor® LAR (pasireotide) injection



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

FDA-approved indication

- Signifor® LAR (pasireotide) 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 (pasireotide) is indicated for the treatment of patients with Cushing's disease for whom pituitary surgery is not an option or is not 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 patient must meet ONE of the following (A or B):

- A. Initial therapy: The patient meets ALL of the following criteria (i, ii, and iii)
 - i. The patient meets ONE of the following criteria (a, b, or c):
 - a. The patient has had an inadequate response to surgery and/or radiotherapy; OR
 - b. The patient is not an appropriate candidate for surgery and/or radiotherapy; OR
 - c. The patient is experiencing negative effects due to tumor size (e.g., optic nerve compression); AND
 - ii. The medication is prescribed by or in consultation with an endocrinologist: AND
 - iii. The patient has (or had) a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal (ULN) based on age and gender for the reporting laboratory.
- B. Patient is Currently Receiving Signifor LAR: The patient has responded to Signifor LAR (e.g., decrease/normalization of IGF-1 level, decrease in growth hormone level, improvement in metabolic abnormalities [e.g., diabetes mellitus]), as determined by the prescriber

Approval Duration (initial): 3 months

Approval Duration (renewal): 12 months

Cushing's disease:

The individual must meet ONE of the following (A or B):

- A. Initial therapy: The patient meets BOTH of the following criteria (i and ii):

- i. The medication is being prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of Cushing's disease; AND
 - ii. The patient is not a candidate for pituitary surgery or surgery has not been curative, as per the prescribing physician; OR
- B. Patient is Currently Receiving Signifor/Signifor LAR: The patient has responded to Signifor/Signifor LAR (e.g., decrease in the mean urinary free cortisol level), as determined by the prescriber and the patient is continuing therapy to maintain response.

Approval Duration (initial): 4 months

Approval Duration (renewal): 12 months

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

- The medication is being prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of Cushing's disease.

Approval Duration (initial and renewal): 4 months

Dosing Recommendations

Acromegaly:

- Initial dose is 40mg IM once every 4 weeks (every 28 days)
- The dose may be increased to a maximum of 60mg for patients who have not normalized GH and/or age and sex adjusted IGF-1 levels after 3 months of treatment with Signifor LAR at 40mg.

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

- The recommended initial dose is 10 mg IM once every 4 weeks (every 28 days).
- 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]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2018.
2. Katznelson L, Laws ER Jr, Melmed S, et al; Endocrine Society. Acromegaly: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2014; 99:3933-3951.
3. Nieman LK, Biller BM, Findling JW, et al. Treatment of Cushing's syndrome: An Endocrine Society Clinical Practice Guidelines. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4525003/?report=reader>. Accessed on August 7, 2018.
4. Tritos NA, Biller BM. Advances in medical therapies for Cushing's syndrome. Discov Med. 2012; 13(69):171-179.
5. Mazziotti G, Gazzaruso C and Giustina A. Diabetes in Cushing syndrome: basic and clinical aspects. Trends Endocrinol Metab. 2011; 22(12):499-506.
6. Rizk A, Honegger J, Milian M and Psaras T. Treatment options in Cushing's disease. Clin Med Insights Oncol. 2012(6):75-84.