

Signifor® (pasireotide) Injection

When requesting Signifor (pasireotide) injection, the individual requiring treatment must be diagnosed with the following approved indication or compendial use and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

FDA-approved Indication

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

Approved Off-label Compendial Use

Treatment of endogenous Cushing's syndrome in adult individuals awaiting surgery or awaiting therapeutic response after receiving radiotherapy.

Coverage Guidelines

Cushing's disease

The individual must meet **all** of the following criteria for initial authorization:

- Is 18 years of age or older;
- Is not a candidate for surgery or surgery has not been curative; AND
- Signifor is prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of Cushing's syndrome.

Approval duration: 4 months

For reauthorization, the individual must have responded to Signifor/Signifor LAR therapy and is continuing Signifor to maintain response.

Approval Duration: 12 months

Endogenous Cushing's syndrome (in patients awaiting surgery or awaiting therapeutic response after radiotherapy)

The individual must meet **all** of the following criteria for authorization:

- Is 18 years of age or older; AND
- Signifor is prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of Cushing's disease.

Approval Duration: 4 months

Dosing Recommendations

Initial dosing is 0.3mg-0.9mg by subcutaneous injection twice a day. In patients with hepatic impairment (Child-Pugh B), start with 0.3mg twice a day and titrate to 0.6mg twice a day.

References

1. Signifor® injection [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2020.
2. Tritos NA, Biller BM. Advances in medical therapies for Cushing's syndrome. *Discov Med*. 2012;13(69):171-179.
3. Biller BMK, Grossman AB, Stewart PM, et al. Treatment of adrenocorticotropin-dependent Cushing's syndrome: consensus statement. *J Clin Endocrinol Metab*. 2008;93:2454-2462.
4. Arnaldi G and Boscaro M. New treatment guidelines on Cushing's disease. *F1000 Med Rep*. 2009;1.
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.
7. 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.