Reference number(s)
2124-A

Specialty Guideline Management Signifor

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Signifor	pasireotide

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

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

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- For initial requests, pretreatment cortisol level as measured by one of the following tests:
  - Urinary free cortisol (UFC)
  - Late-night salivary cortisol (LNSC)
  - 1 mg overnight dexamethasone suppression test (DST)

    - Longer, low dose DST (2 mg per day for 48 hours)
- For continuation of therapy requests (if applicable), laboratory report indicating current cortisol level has decreased from baseline as measured by one of the following tests:
    - Urinary free cortisol (UFC)
    - Late-night salivary cortisol (LNSC)
    - 1 mg overnight dexamethasone suppression test (DST)
    - Longer, low dose DST (2 mg per day for 48 hours)
    - Morning serum cortisol

Prescriber Specialties

This medication must be prescribed by or in consultation with an endocrinologist or a prescriber specialized in the treatment of Cushing's disease.

Coverage Criteria

Cushing's Disease[1-3]

Authorization of 12 months may be granted for treatment of Cushing's disease in adult members who meet both of the following:

- Member's diagnosis is confirmed by one of the following tests:
    - Urinary free cortisol (UFC)
    - Late-night salivary cortisol (LNSC)
    - 1 mg overnight dexamethasone suppression test (DST)
    - Longer, low dose DST (2 mg per day for 48 hours)
- Member has had surgery that was not curative or member is not a candidate for surgery.

Continuation of Therapy

Cushing's Disease[1-3]

Authorization of 12 months may be granted for adult members that meet one of the following criteria:

- Lower cortisol levels since the start of therapy per one of the following tests:
    - Urinary free cortisol (UFC)
    - Late-night salivary cortisol (LNSC)
    - 1 mg overnight dexamethasone suppression test (DST)

    - Longer, low dose DST (2 mg per day for 48 hours)
    - Morning serum cortisol
- Improvement in signs or symptoms of the disease

References

1. Signifor [package insert]. Bridgewater, NJ: Recordati Rare Diseases Inc.; July 2024.
2. Nieman LK, Biller BM, Findling JW, et al. Treatment of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2015;100(8):2807-2831. doi:10.1210/jc.2015-1818
3. 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. doi:10.1016/S2213-8587(21)00235-7