Reference number(s)
2124-A

SPECIALTY GUIDELINE MANAGEMENT

SIGNIFOR (pasireotide)

POLICY

I. 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 Indication
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.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
A. For initial requests, pretreatment cortisol level as measured by one of the following tests:
   1. Urinary free cortisol (UFC)
   2. Late-night salivary cortisol (LNSC)
   3. 1 mg overnight dexamethasone suppression test (DST)
   4. Longer, low dose DST (2 mg per day for 48 hours)
B. 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:
   1. Urinary free cortisol (UFC)
   2. Late-night salivary cortisol (LNSC)
   3. 1 mg overnight dexamethasone suppression test (DST)
   4. Longer, low dose DST (2 mg per day for 48 hours)

III. CRITERIA FOR INITIAL APPROVAL

Cushing's disease
Authorization of 6 months may be granted for treatment of Cushing's disease in members who either have had surgery that was not curative OR for members who are not candidates for surgery.

IV. CONTINUATION OF THERAPY

Cushing's disease
Authorization of 12 months may be granted for members that meet one of the following criteria:
A. Lower cortisol levels since the start of therapy per one of the following tests:
   1. Urinary free cortisol (UFC)
   2. Late-night salivary cortisol (LNSC)
   3. 1 mg overnight dexamethasone suppression test (DST)

4. Longer, low dose DST (2 mg per day for 48 hours)

B. Improvement in signs or symptoms of the disease

V. REFERENCES

1. Signifor [package insert]. Lebanon, NJ: Recordati Rare Diseases; March 2020.
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