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

Cushing's syndrome/disease
Submission of the following information is necessary to initiate the prior authorization review:

A. For initial requests, either of the following:
   1. Pretreatment urinary free cortisol (UFC) level
   2. One of the following if UFC level is not an appropriate measure due to the member's condition (e.g., renal insufficiency/failure, adrenal incidentaloma)
      a. Pretreatment late-night salivary cortisol
      b. Pretreatment 1 mg overnight dexamethasone suppression test (DST)
      c. Pretreatment longer, low dose DST (2mg per day for 48 hours)

B. For continuation of therapy, either of the following:
   1. Current urinary free cortisol (UFC) level
   2. One of the following if UFC level is not an appropriate measure due to the member's condition (e.g., renal insufficiency/failure, adrenal incidentaloma)
      a. Current late-night salivary cortisol
      b. Current 1 mg overnight dexamethasone suppression test (DST)
      c. Current longer, low dose DST (2mg per day for 48 hours)

III. CRITERIA FOR APPROVAL

Cushing's syndrome/disease
Authorization of 6 months may be granted for the treatment of Cushing's disease/syndrome 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 syndrome/disease
Authorization of 12 months for continuation of therapy may be granted for members that meet one of the following criteria:
A. Lower urinary free cortisol levels since the start of therapy
B. Lower cortisol levels since the start of therapy per one of the following tests (if UFC is not an appropriate measure due to the member's condition):
    1. Late-night salivary cortisol
    2. 1 mg overnight dexamethasone suppression test (DST)
    3. Low dose DST (2mg per day for 48 hours)
C. Improvement in signs or symptoms of the disease

V. REFERENCES

1. Signifor [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2020.
2. Nieman LK, Biller B, Findling JW, et al. Treatment of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2015;100:2807-2831.