AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Signifor	Page:	1 of 2
Effective Date:	8/19/2024	Last Review Date:	7/2024

Applies to:	☐Illinois	☐Florida	☒Florida Kids
	☒New Jersey	☒Maryland	☐Michigan
	☒Pennsylvania Kids	☒Virginia	☒KY PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Signifor under the patient's prescription drug benefit.

Description:

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.

Applicable Drug List:

Signifor

Policy/Guideline:

Documentation:
Cushing's disease
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
   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, current cortisol level as measured by one of the following tests:
   1. Urinary free cortisol (UFC)
   2. Late-night salivary cortisol
   3. 1 mg overnight dexamethasone suppression test (DST)
   4. Longer, low dose DST (2 mg per day for 48 hours)

Criteria for Initial Approval:
Authorization of 6 months may be granted for members that meet all of the following criteria:

A. For the 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
B. The member is unable to take Octreotide Acetate Injection followed by Sandostatin Long Acting Release (LAR) for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval.

Continuation of Therapy:
Cushing's disease
Authorization of 12 months for continuation of therapy 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
   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

Approval Duration and Quantity Restrictions:

Approval:
Initial: 6 months
Renewal: 12 months

Quantity Level Limit: 60 ampules/30 days

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