Commercial/Healthcare Exchange PA Criteria

Effective: July 27, 2016

Prior Authorization: Signifor

Products Affected: Signifor (pasireotide diaspartate) subcutaneous injection

Medication Description:

Signifor is an injectable cyclohexapeptide somatostatin analogue indicated for the treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative. Pasireotide exerts its pharmacological activity via binding to somatostatin receptors (SSTRs). Five human somatostatin receptor subtypes are known: SSTR 1, 2, 3, 4, and 5. These receptor subtypes are expressed in different tissues under normal physiological conditions. Corticotroph tumor cells from Cushing's disease patients frequently over-express SSTR5 whereas the other receptor subtypes are often not expressed or are expressed at lower levels. Pasireotide binds and activates the SSTRs resulting in inhibition of ACTH secretion, which leads to decreased cortisol secretion.

Patients should be evaluated for a treatment response [clinically meaningful reduction in 24-hour urinary free cortisol (UFC) levels and/or improvement in signs or symptoms of the disease] and should continue receiving therapy with Signifor as long as benefit is derived. Maximum urinary free cortisol reduction is typically seen by two months of treatment. For patients who are started on 0.6 mg twice a day, a dosage increase to 0.9 mg twice a day may be considered based on the response to the treatment, as long as the 0.6 mg dosage is well tolerated by the patient.

Covered Uses: Cushing's disease where pituitary surgery is not an option or has not been curative

Exclusion Criteria: N/A

Required Medical Information:

1. Diagnosis
2. Documentation of surgical history, hemoglobin A1c, and plasma glucose levels

Age Restrictions: 18 years of age or older

Prescriber Restrictions: Prescribed by, or in consultation with, an endocrinologist.

Coverage Duration: 12 months

Other Criteria:

A. The patient has a documented diagnosis of persistent or recurrent Cushing's disease; **AND**
B. Pituitary surgery is not an option **OR** has not been curative for the patient; **AND**
C. The patient's hemoglobin A1c and plasma glucose levels are well controlled.

References:

1. Signifor prescribing information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 2015 March.
2. Colao A, Petersen S, Newell-Price J, et al. A 12-month phase 3 study of pasireotide in Cushing's disease. N Engl J Med. 2012; 366:914-24.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	5/3/16
2	Annual Review	CCI adopted EH Policy and template. Removed from CCI PA to Indication Policy	All	12/11/19