UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Signifor

Program	Prior Authorization
Medication	Signifor® (pasireotide diaspartate)
Pharmacy & Therapeutics Approval Date	9/2016
Effective Date	11/2016

1. Background:

Signifor (pasireotide diaspartate) is a somatostatin analog indicated for the treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative.[1]

2. Coverage Criteria:

A. Initial Authorization

1. **Signifor** will be approved based on **both** of the following criteria:

   a. Diagnosis of endogenous Cushing's disease (i.e., hypercortisolism is not a result of chronic administration of high dose glucocorticoids)

   -AND-

   b. **One** of the following:

   (1) Pituitary surgery has not been curative for the patient
   (2) Patient is not a candidate for pituitary surgery

Authorization will be issued for 12 months.

B. Reauthorization

1. Signifor will be approved based on the following criterion:

   a. Documentation of positive clinical response to Signifor therapy

Authorization will be issued for 12 months.

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3. Additional Clinical Rules:

- Supply limits may be in place.

4. References:

1. Signifor [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2015.

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Change Control	
Date	Change
3/2013	New guideline
3/2015	▪ Updated the existing Signifor guideline to include new prior authorization criteria for Signifor LAR, which is indicated for the treatment acromegaly. o Initial authorization requires diagnosis of acromegaly by one of the following: serum GH level > 1 ng/mL after a 2 hour oral glucose tolerance test (OGTT) at the time of diagnosis OR elevated serum IGF-1 levels (above the age and gender adjusted normal range as provided by the physician's lab) at the time of diagnosis. The patient must also have had an inadequate response to surgery or the patient is not a candidate for surgery. o Reauthorization requires documentation of positive clinical response to Signifor LAR therapy.
9/2016	Updated policy template and clinical criteria to align with E&I, including removal of Signifor LAR

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