BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

MEDICAL COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 09/17/13
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SIGNIFOR® (pasireotide diaspartate)

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

Signifor® is an injectable cyclohexapeptide somatostatin analogue indicated for the treatment of individuals with Cushing's disease. Cushing's syndrome is an endocrine disorder caused by excessive cortisol, a vital hormone that regulates metabolism, maintains cardiovascular function and helps the body respond to stress. Cushing's disease is a form of Cushing's syndrome, in which excess cortisol production is triggered by a pituitary adenoma secreting excess adrenocorticotropic hormone (ACTH).

SIGNIFOR (pasireotide diaspartate) (cont.)

Criteria:

- FDA approved dosage of Signifor for treatment of Cushing's disease is considered ***medically necessary*** with documentation of **ALL** of the following:

  1. Individual is 18 years or older
  2. Pituitary surgery has not been curative or individual is not a candidate for pituitary surgery.
  3. Prior to the start of Signifor, a baseline level of the following:

     - Electrocardiogram (EKG)
     - Fasting plasma glucose
     - Gallbladder ultrasound
     - Hemoglobin AIc (HbA1c)
     - Liver function tests

  4. Treatment of individuals with poorly controlled diabetes mellitus should be intensively optimized with anti-diabetic therapy

- Signifor for all other indications not previously listed is considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

Resources:

FDA Product Approval Information for Signifor:

- FDA-approved indication: For the treatment of individuals with Cushing's disease for whom pituitary surgery is not an option or has not been curative.

- FDA approved dosage: Signifor is administered as a subcutaneous injection. The recommended initial dosage is either 0.6 mg or 0.9 mg twice a day. Titrate dosage based on treatment response (clinically meaningful reduction in 24 hour urinary free cortisol (UFC) and/or improvements in signs and symptoms of disease) and tolerability.

Safety and effectiveness of Signifor in children under 18 years have not been established.