Signifor LAR (pasireotide pamoate)

Override(s)	Approval Duration
Prior Authorization	1 year
Quantity Limit	

Quantity Limit
May be subject to quantity limit

APPROVAL CRITERIA

Requests for Signifor LAR (pasireotide pamoate) may be approved if the following criteria are met:

- I. Documentation is provided that individual has a diagnosis of acromegaly; AND
- II. Diagnosis of acromegaly has been confirmed by, or in consultation with, a boardcertified endocrinologist who has reviewed and verified the test results (including but not limited to: Insulin-like Growth Factor 1 levels; Oral Glucose Tolerance Test with associated Growth Hormone (GH) levels) that are indicative of a positive test; **AND**
- III. Individual has had an inadequate response to surgery and/or surgery is not an option (such as but not limited to, individual is an inappropriate candidate for surgical-based therapy);

OR

- IV. Documentation is provided that individual has a diagnosis of Cushing's disease; **AND**
- V. Diagnosis of Cushing's has been confirmed by, or in consultation with, a boardcertified endocrinologist who has reviewed and verified the test results (including but not limited to: 24-hour urinary free cortisol (UFC) test; Dexamethasone suppression test (DST); Late-night salivary cortisol (LNSC) test) that are indicative of a positive test; AND
- VI. One of the following:
 - A. Disease persists or recurs following pituitary surgery; OR
 - B. Pituitary surgery is not indicated or an option.

Requests for Signifor LAR (pasireotide pamoate) may not be approved for the following:

I. Individual has a diagnosis of severe hepatic impairment (Child Pugh C).

Key References:

- 1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: <u>http://www.clinicalpharmacology.com</u>. Updated periodically.
- 2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 8, 2022.
- 3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
- 4. Lexi-Comp ONLINE[™] with AHFS[™], Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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