Medical Drug Clinical Criteria

Subject:	Signifor LAR (pasireotide)		
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Table of Contents

Overview

This document addresses the use of Signifor LAR (pasireotide pamoate). Signifor LAR is indicated for both acromegaly and Cushing's syndrome. Signifor LAR is a long-acting release pasireotide agent. Pasireotide agents binds to somatostatin receptors (SSTRs) and have pharmacologic properties mimicking those of the natural hormone somatostatin. Signifor LAR must be administered by a healthcare professional by intramuscular injection and never administered intravenously. Signifor LAR can cause increases in blood glucose levels which are sometimes severe.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Signifor LAR (pasireotide pamoate)

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~~ verified by, or in consultation with, a board-certified endocrinologist who has reviewed and verified the test results (~~such as~~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~~including 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~~ verified by, or in consultation with, a board-certified endocrinologist who has reviewed and verified the test results (~~such as~~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.

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

I. Individual has a diagnosis of severe hepatic impairment (Child Pugh C); OR
~~I.~~II. When the above criteria are not met and for all other indications.

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Quantity Limits

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Drug	Limit
Signifor LAR (pasireotide pamoate) Kit 10 mg, 20 mg, 30 mg, 40 mg, 60 mg	1 kit per 28 days

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J2502	Injection, pasireotide long acting, 1 mg [Signifor LAR]

ICD-10 Diagnosis

E24.0-E24.9	Cushing's Syndrome
E22.0	Acromegaly and pituitary gigantism

Document History

Revised: 09/11/2023
Document History:

- 09/11/2023 – Annual Review: Wording and formatting changes. Coding Reviewed: No changes.
- 04/04/2023 – Add new clinical criteria document for Signifor LAR. Coding Reviewed: Added HCPCS J2502. Added ICD-10-CM E24.0-E24.9, E22.0.

References

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: June 14, 2022.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. 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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