

Policy Name:	Signifor and Signifor LAR (pasireotide)	Policy #:	2421P
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Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Signifor and Signifor LAR.

Statement of the Policy

Health Alliance Medical Plans will approve the use of Signifor for the treatment of Cushing's Syndrome under the specialty pharmacy benefit or Signifor LAR for the treatment of Acromegaly under the specialty medical benefit when the following criteria have been met.

Criteria

1. Criteria for Initial Coverage of Signifor for the Treatment of Cushing's Syndrome

- 1.1 Diagnosis of Cushing's syndrome/disease
- 1.2 Documentation that the member underwent a surgical procedure which was not curative or that the member is not a candidate for surgery
- 1.3 Signifor is prescribed by or in consultation with an endocrinologist (hormone doctor)
- 1.4 Submission of baseline fasting plasma glucose and/or HbA1c levels which show controlled glucose levels, OR
 - Signifor may increase blood sugar levels
- 1.5 Documentation which shows the member's glucose levels are not controlled while on maximum antidiabetic therapy
 - Signifor may increase blood sugar levels

2. Criteria for Continued coverage of Signifor for the Treatment of Cushing's Syndrome

- 2.1 Documentation of a clinically meaningful reduction in 24-hour urinary free cortisol (UFC) levels,
- 2.2 Documentation of continued controlled blood glucose levels, OR
- 2.3 Documentation that the member's glucose levels are not controlled while on maximum antidiabetic therapy.

3. Criteria for coverage of Signifor LAR for the Treatment of Acromegaly

- 3.1 Prescribed by an endocrinologist (hormone doctor)
- 3.2 Diagnosis of acromegaly
- 3.3 Documented high growth factor hormone (IGF-1) for age
- 3.4 Lab-specific values
- 3.5 Documented inadequate response to surgery or radiotherapy or clinical reason why the patient has not had surgery or radiotherapy
- 3.6 Documented failure of or contraindication to Sandostatin or Sandostatin LAR

4. Approval Period

- 4.1 Initial: 12 months
- 4.2 Reauthorization: 12 months

CPT Codes

96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
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HCPCS Codes

J2502	Injection, pasireotide long-acting, 1 mg
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References

1. Signifor (pasireotide) [prescribing information]. Lebanon, NJ: Recordati Rare Diseases Inc; March 2020.
2. Signifor LAR (pasireotide) [prescribing information]. Lebanon, NJ: Recordati Rare Diseases Inc; June 2020.
3. Fleseriu M, Biller BMK, Freda PU, et al. A Pituitary Society update to acromegaly management guidelines. *Pituitary*. 2021 Feb;24(1):1-13.
4. Giustina A, Barkan A, Beckers A, et al. A Consensus on the Diagnosis and Treatment of Acromegaly Comorbidities: An Update. *J Clin Endocrinol Metab*. 2020 Apr 1;105(4):dgz096.
5. Fleseriu M, Auchus R, Bancos I, et al. Consensus on diagnosis and management of Cushing's disease: a guideline update. *Lancet Diabetes Endocrinol*. 2021 Dec;9(12):847-875.
6. Nieman LK, Biller BM, Findling JW, et al; Endocrine Society. Treatment of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2015 Aug;100(8):2807-31.

Created Date: 12/02/15

Effective Date: 12/02/15

Posted to Website: 01/01/22

Revision Date: 06/05/24

DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.