

**Pharmacy Policy**

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**Signifor**

**Policy Number:** 9.306

**Version Number:** 1

**Version Effective Date:** 1/1/2021

<b>Product Applicability</b> <input type="checkbox"/> <b>All Plan+ Products</b>	
<b>Well Sense Health Plan</b> <input type="checkbox"/> New Hampshire Medicaid	<b>Boston Medical Center HealthNet Plan</b> <input checked="" type="checkbox"/> MassHealth- MCO <input checked="" type="checkbox"/> MassHealth- ACO <input type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct <input type="checkbox"/> Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

**Prior Authorization Policy**

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**Products Affected:**

- **Signifor (pasireotide)**
- **Signifor LAR (pasireotide ER)**

The Plan may authorize coverage of the above products for members meeting the following criteria:

<b>Covered Use</b>	All medically excepted indications unless otherwise excluded
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	<b>Signifor</b> 1. Diagnosis of Cushing’s disease; AND 2. Pituitary surgery is not an option OR pituitary surgery has not been curative; AND 3. Baseline 24-hour urine free cortisol level is ≥ 1.5 times the upper limit of normal;

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	<p>AND</p> <p>4. Inadequate response, intolerance, or contraindication to at least one of the following: ketoconazole, cabergoline, or mitotane.</p> <p><b>Signifor LAR</b></p> <p>1. Diagnosis of acromegaly; <b>AND</b></p> <p>a. Persistent disease despite surgery or surgery is not an option; <b>AND</b></p> <p>b. Normal glucose tolerance; <b>AND</b></p> <p>c. An inadequate response, contraindication, or adverse reaction to octreotide; <b>OR</b></p> <p>2. Diagnosis of Cushing's disease; <b>AND</b></p> <p>a. Pituitary surgery is not an option OR pituitary surgery has not been curative; <b>AND</b></p> <p>b. Baseline 24-hour urine free cortisol level is <math>\geq 1.5</math> times the upper limit of normal; <b>AND</b></p> <p>c. Inadequate response, intolerance, or contraindication to at least one of the following: ketoconazole, cabergoline, or mitotane.</p>
<b>Age Restrictions</b>	Greater than 18 years of age
<b>Prescriber Restriction</b>	Endocrinologist or in conjunction with an endocrinologist
<b>Coverage Duration</b>	Initial: 6 months Reauthorization: Maximum of 12 months
<b>Other criteria</b>	Re-authorization
	<p>1. 24-hour urine free cortisol level is <math>&lt; 1.5</math> times the upper limit of normal; AND</p> <p>2. Patient is tolerating therapy</p>

#### Applicable Coding:

Code	Medication
J2502	pasirotide long-acting injection

#### Clinical Background Information and References

1. Signifor [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2012.

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2. Signifor LAR [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2014.
3. Biller BMK, Grossman AB, Stewart PM, Melmed S, Bertagna X, Bertherat M, et al. Treatment of adrenocorticotropin-dependent Cushing's syndrome: a consensus statement. J Clin Endocrinol Metab. 2008;93(7):2454-2462.
4. Gadelha MR, Neto LV. Efficacy of medical treatment in Cushing's disease: a systematic review. Clin Endocrin. 2014;80:1-12.
5. Colao A, Petersenn S, Newell-Price J, Findling JW, Gu F, Maldonado M, et al. A 12-month phase 3 study of pasireotide in Cushing's disease. NEJM. 2012;366:914-924.
6. Melmed S. Treatment of acromegaly. UptoDate. Last updated May 22, 2015, accessed June 11, 2017.
7. Melmed S. Diagnosis of acromegaly. UptoDate. Accessed 17 June 2016.
8. Shlomo Melmed, MD Laurence Katznelson, MD. Treatment of Acromegaly. UptoDate. Last updated January 8, 2018. Accessed June 6, 2018.
9. Lynnette K Nieman, MD. Overview of treatment of Cushing's Syndrome. UptoDate. Last updated November 28, 2017. Accessed June 6, 2018.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date	Approved by
12/1/2020	9.049 Signafor Policy retired, new policy created	1/1/2021	P&T Committee

**Next Review Date**

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2021

**Other Applicable Policies**

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### Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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