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Pharmacy Policy

Signifor

Policy Number: 9.306
Revision Number: R0
Version Effective Date: 1/1/2021

Product Applicability	☐ **All Plan[+] Products**
Well Sense Health Plan	**Boston Medical Center HealthNet Plan**
☒ New Hampshire Medicaid	☐ MassHealth- MCO
☐ _____	☐ MassHealth- ACO
	☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct
	☐ Senior Care Options
	☐ _____

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

Prior Authorization Policy

Products Affected:

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

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

Covered Use	All medically excepted indications unless otherwise excluded
Exclusion Criteria	None
Required Medical Information	**Signifor** Documentation of the following: 1. Diagnosis of Cushing's disease; AND

[+] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

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

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.
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 Endrocinol 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, MDLaurence 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, NH DHHS

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, NH DHHS

Next Review Date

2021

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

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.