

Signifor LAR (pasireotide injectable suspension)
Effective 03/01/2023

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations			
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions			

Overview

Signifor LAR (pasireotide injectable suspension) is indicated for the treatment of patients with acromegaly who have had an inadequate response to surgery and/or for whom surgery is not an option and Cushing's disease for whom pituitary surgery is not an option or has not been curative.

Coverage Guidelines

Authorization may be granted for new members to the plan who are currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

Acromegaly

1. Member has a high pretreatment IGF-1 level for age and/or gender based on the laboratory reference range.
2. Member had an inadequate or partial response to surgery OR there is a clinical reason why the member has not had surgery

Cushing's syndrome

1. Member has had surgery that was not curative OR the member is not a candidate for surgery.

Continuation of Therapy

Acromegaly: Reauthorization requires physician documentation for continuation of therapy when the member's IGF-1 level has decreased or normalized since initiation of therapy.

Cushing's syndrome/disease: Reauthorization requires physician documentation for continuation of therapy when members meet ONE of the following:

1. Lower cortisol levels since the start of therapy for ONE of the following tests:
 - a. Urinary free cortisol (UFC)
 - b. Late-night salivary cortisol
 - c. 1 mg overnight dexamethasone suppression test (DST)
 - d. Longer, low dose DST (2 mg per day for 48 hours)
2. Improvement in signs and symptoms of the disease

Limitations

1. Initial approvals and reauthorizations will be granted for 12 months.

References

1. Signifor LAR [package insert]. Lebanon, NJ: Recordati Rare Diseases Inc.; June 2020.
2. Katznelson L, Laws ER Jr, Melmed S, et al. Acromegaly: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2014;99:3933-3951.
3. American Association of Clinical Endocrinologists Acromegaly Guidelines Task Force. Medical guidelines for clinical practice for the diagnosis and treatment of acromegaly – 2011 update. *Endocr Pract.* 2011;17(suppl 4):1-44.
4. Gadelha MR, Bronstein MD, Brue T, et al. Pasireotide versus continued treatment with octreotide or lanreotide in patients with inadequately controlled acromegaly (PAOLA): a randomized, phase 3 trial. *Lancet Diabetes Endocrinol.* 2014;2:875-84.
5. Colao A, Bronstein MD, Freda P, et al. Pasireotide versus octreotide in acromegaly: a head-to-head superiority study. *J Clin Endocrinol Metab.* 2014;99:791–799.
6. Nieman LK, Biller BM, Findling JW, et al. Treatment of Cushing's syndrome: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab.* 2015;100(8):2807-31.
7. Fleseriu M, Auchus R, Bancos I, et al. Consensus on Diagnosis and Management of Cushing's Disease: A Guideline Update. *Lancet Diabetes Endocrinol.* 2021; 9: 847-875

Review History

11/16/2022 – Updated for Nov P&T. Switched to custom. Separated out MH vs Comm/Exch. Effective 03/01/2023.

