Mass General Brigham
Health Plan

Signifor LAR (pasireotide injectable suspension)
Effective 06/01/2023

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

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
3. Member has had inadequate response, intolerable adverse event, or contraindication to Sandostatin LAR and Somatuline Depot

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.
03/15/2023 – Reviewed and Updated for March P&T; Added preferred drugs of Sandostatin LAR and Somatuline Depot as prerequisite prior to Signifor LAR. Effective 6/1/23