

PHARMACY POLICY STATEMENT Common Ground Healthcare Cooperative (CGHC)	
DRUG NAME	Signifor, Signifor LAR (pasireotide)
BENEFIT TYPE	Medical: Signifor LAR Pharmacy: Signifor
STATUS	Prior Authorization Required

Signifor is a second-generation somatostatin analog indicated for the treatment of adult patients with Cushing’s disease for whom pituitary surgery is not an option or has not been curative. Signifor LAR has the same indication for Cushing’s disease, and it is also indicated for patients with acromegaly who have had an inadequate response to surgery and/ or for whom surgery is not an option.

Signifor, Signifor LAR (pasireotide) will be considered for coverage when the following criteria are met:

Cushing’s Disease
<p>For <b>initial</b> authorization:</p> <ol style="list-style-type: none"> <li>Member is 18 years old or older; AND</li> <li>Medication must be prescribed by or in consultation with an endocrinologist; AND</li> <li>Member has a documented diagnosis of Cushing’s disease, with an elevated urinary free cortisol (UFC) level; AND</li> <li>Documentation that pituitary surgery was not curative or surgery is not an option; AND</li> <li>Member has tried and failed a preferred adrenal steroidogenesis inhibitor or cabergoline for at least 2 months at the maximum tolerated dose.</li> <li><b>Dosage allowed/Quantity limit:</b> Signifor: 0.3 mg to 0.9 mg subcutaneously twice daily. Quantity limit: 60 ampules per 30 days. Signifor LAR: 10 mg to 40 mg intramuscularly every 28 days. Quantity limit: 1 vial per 28 days.</li> </ol> <p><b><i>If all the above requirements are met, the medication will be approved for 6 months.</i></b></p>
<p>For <b>reauthorization</b>:</p> <ol style="list-style-type: none"> <li>Chart notes must demonstrate reduced UFC level from baseline.</li> </ol> <p><b><i>If all the above requirements are met, the medication will be approved for an additional 12 months.</i></b></p>

### Acromegaly (Signifor LAR only)

For **initial** authorization:

1. Member is 18 years old or older; AND
2. Medication must be prescribed by or in consultation with an endocrinologist; AND
3. Member has documented diagnosis of uncontrolled acromegaly confirmed by insulin-like growth factor (IGF-1) elevation above normal; AND
4. Documentation of an inadequate response to surgery or surgery is not an option; AND
5. Member has persistent IGF-1 elevation after optimized treatment with octreotide or lanreotide.
6. **Dosage allowed/Quantity limit:** 40 mg to 60 mg intramuscularly every 28 days. Quantity limit: 1 vial per 28 days.

***If all the above requirements are met, the medication will be approved for 6 months.***

For **reauthorization**:

1. Chart notes must demonstrate normalized or improved (decreased) IGF-1.

***If all the above requirements are met, the medication will be approved for an additional 12 months.***

**CareSource considers Signifor, Signifor LAR (pasireotide) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.**

DATE	ACTION/DESCRIPTION
07/06/2020	New policy for Signifor, Signifor LAR created.
03/28/2022	Transferred to new template. The word "second-generation" was added to the summary. Cushing's: Added new reference. Acromegaly: Added new reference, revised language for octreotide/ lanreotide criterion.
03/18/2025	Updated references; removed optimize diabetic therapy for diabetic patients criteria Acromegaly: removed three-month trial length. Cushing's: changed trial length from three-months to two-months at the maximum tolerated dose per Fleseriu M (2021) et al; replaced trial of ketoconazole and/or cabergoline with trial of a preferred adrenal steroidogenesis inhibitor or cabergoline per Fleseriu M (2021) et al.

#### References:

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2. Signifor LAR [package insert]. Recordati Rare Diseases, Inc; 2024.
3. 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):2807-2831. doi:10.1210/jc.2015-1818
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5. Colao A, Petersenn S, Newell-Price J, et al. A 12-month phase 3 study of pasireotide in Cushing's disease [published correction appears in *N Engl J Med*. 2012 Aug 23;367(8):780]. *N Engl J Med*. 2012;366(10):914-924. doi:10.1056/NEJMoa1105743
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10. Sheppard M, Bronstein MD, Freda P, et al. Pasireotide LAR maintains inhibition of GH and IGF-1 in patients with acromegaly for up to 25 months: results from the blinded extension phase of a randomized, double-blind, multicenter, Phase III study [published correction appears in *Pituitary*. 2015 Jun;18(3):395-6]. *Pituitary*. 2015;18(3):385-394. doi:10.1007/s11102-014-0585-6
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12. 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(12):847-875. doi:10.1016/S2213-8587(21)00235-7
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