CareSource

PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Signifor, Signifor LAR (pasireotide)
BILLING CODE	Must use valid NDC code (Signifor) or J2502 (Signifor LAR)
BENEFIT TYPE	Medical (Signifor LAR) or Pharmacy (Signifor)
SITE OF SERVICE ALLOWED	Home (Signifor), Office/Outpatient (Signifor LAR)
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Products) QUANTITY LIMIT— See "Dosage allowed"
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Signifor, Signifor LAR (pasireotide) are **non-preferred** products and will only be considered for coverage under the **medical or pharmacy** benefit (see above) when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

CUSHING'S DISEASE

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 a diagnosis of Cushing's disease, with an elevated urinary free cortisol (UFC) level (lab report required); AND
4. Member had pituitary surgery and it was not curative OR member is not a candidate for surgery (documentation required); AND
5. If the member has uncontrolled diabetes, anti-diabetic therapy must be optimized before starting treatment (as evidenced by consistent fill history); AND
6. Member has tried and failed ketoconazole and/or cabergoline for at least 3 months.
7. **Dosage allowed:** Signifor: 0.9mg subQ twice daily (60 ampules per 30 days). Signifor LAR: 40mg IM every 28 days (1 vial per 28 days)

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Member does not have unmanageable adverse effects; AND
2. Chart notes must show reduced UFC level from baseline; AND
3. Chart notes must show improved signs and symptoms compared to baseline.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

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 diagnosis of uncontrolled acromegaly confirmed by insulin-like growth factor (IGF-1) elevation above normal (lab report required); AND
4. Member had an inadequate response to surgery or surgery is not an option (documentation required); AND
5. If the member has uncontrolled diabetes, anti-diabetic therapy must be optimized before starting treatment (as evidenced by consistent fill history); AND
6. Member remains uncontrolled (persistent IGF-1 elevation) after optimized treatment with octreotide for at least 3 months[11]. (Lanreotide is also acceptable, but not a preferred product).
7. **Dosage allowed:** 60mg every 28 days (1 vial per 28 days)

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Member does not have unmanageable adverse effects; AND
2. Chart notes/lab report must show normalized or improved (decreased) IGF-1.[8,9]

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Signifor/Signifor LAR (pasireotide) not medically necessary for the treatment of diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
07/06/2020	New policy for Signifor, Signifor LAR created.

References:

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2. Signifor LAR [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 2020.
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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

11. Melmed S, Bronstein MD, Chanson P, et al. A Consensus Statement on acromegaly therapeutic outcomes. *Nature Reviews Endocrinology*. 2018;14(9):552-561. doi:10.1038/s41574-018-0058-5

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