CareSource

PHARMACY POLICY STATEMENT
North Carolina Marketplace

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)
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

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/Quantity limit:**
   Signifor: 0.3 mg to 0.9 mg subQ twice daily (60 ampules per 30 days)
   Signifor LAR: 10 mg to 40mg IM every 28 days (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 show reduced UFC level from baseline; AND
2. Chart notes must show improved signs and symptoms compared to baseline.

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

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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 or lanreotide for at least 3 months[11].
7. **Dosage allowed/Quantity limit:** 40 mg to 60mg every 28 days (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/lab report must show normalized or improved (decreased) IGF-1.[8,9]

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.

References:

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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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13. Fleseriu M, Biller BMK, Freda PU, et al. A Pituitary Society update to acromegaly management guidelines. *Pituitary*. 2021;24(1):1-13. doi:10.1007/s11102-020-01091-7

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