Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 11/01/2021**
Policy Number: PA.CP.PHAR.332	**Effective Date: 01/2020** **Revision Date: 10/2021**
Policy Name: Pasireotide (Signifor, Signifor LAR)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

4Q 2021 annual review: no significant changes; updated J code; references reviewed and updated

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:**

Clinical Policy: Pasireotide (Signifor, Signifor LAR)

Reference Number: PA.CP.PHAR.332
Effective Date: 01.18
Last Review Date: 10/2021

Coding Implications
Revision Log

Description
Pasireotide (Signifor®, Signifor® LAR) is a somatostatin analog.

FDA Approved Indication(s)
Signifor is 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 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
- Cushing's disease for whom pituitary surgery is not an option or has not been curative

Policy/Criteria
It is the policy of health plans affiliated with Pennsylvania Health and Wellness® that Signifor and Signifor LAR is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Acromegaly (must meet all):
1. Diagnosis of acromegaly;
2. Prescribed by or in consultation with an endocrinologist;
3. Age ≥ 18 years;
4. Request is for Signifor LAR;
5. Inadequate response to surgical resection or pituitary irradiation (*see Appendix D*), or member is not a candidate for such treatment;
6. Dose does not exceed 60 mg every 4 weeks (1 vial every 4 weeks).

Approval duration: 6 months

B. Cushing's Disease (must meet all)**:**
1. Diagnosis of Cushing's disease;
2. Prescribed by or in consultation with an endocrinologist;
3. Age ≥ 18 years;
4. Member meets one of the following (a or b):
   a. Pituitary surgery was not curative;
   b. Ineligible for pituitary surgery;
5. Dose does not exceed one of the following (a or b):
   a. Signifor: 1.8 mg per day (2 ampules of 0.9mg per day);
   b. Signifor LAR: 40 mg every 4 weeks (1 vial every 4 weeks).

Approval duration: 6 months

C. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

A. Acromegaly (must meet all):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy (*see Appendix D*);
3. Request is for Signifor LAR;
4. If request is for a dose increase, new dose does not exceed 60 mg every 4 weeks (1 vial every 4 weeks).

Approval duration: 12 months

B. Cushing's Disease (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy (see Appendix D);
3. If request is for a dose increase, new dose does not exceed one of the following:
    a. Signifor: 1.8 mg per day (2 ampules of 0.9 mg) per day;
    b. Signifor LAR: 40 mg (1 vial) every 4 weeks.

Approval duration: 12 months

C. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53
    a. The requested dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
None reported

Appendix D: General Information

- Treatment response for Cushing's disease may be defined as reduction in 24-hour urinary free cortisol (UFC) levels and/or improvement in signs or symptoms of the disease. Maximum urinary free cortisol reduction is typically seen by two months of treatment.
- Examples of treatment response to acromegaly therapy (including somatostatin analogs, surgical resection or pituitary irradiation) include improvement from baseline in or normalization of growth hormone (GH) and/or age- and sex-adjusted insulin-like growth factor (IGF-1) serum concentrations, or tumor mass control.

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Pasireotide (Signifor)	Cushing's disease	Initial: 0.6 mg or 0.9 mg SC BID Recommended dosing range: 0.3 mg to 0.9 mg SC BID	1.8 mg/day
Pasireotide (Signifor LAR)*	Cushing's disease	10 mg to 40 mg IM every 4 weeks	40 mg/4 weeks
Pasireotide (Signifor LAR)*	Acromegaly	40 mg to 60 mg IM every 4 weeks	60 mg/4 weeks

**Signifor LAR must be administered by a healthcare professional*

IV. Product Availability

Drug Name	Availability
Pasireotide (Signifor)	Single-dose ampules for injection: 0.3 mg/mL, 0.6 mg/mL, 0.9 mg/mL
Pasireotide (Signifor LAR)	Vial for reconstitution and injectable suspension: 10 mg, 20 mg, 30 mg, 40 mg, 60 mg

VI. References

1. Signifor Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2020. Available at: https://www.signifor.com/pdf/signifor-pi.pdf. Accessed August 12, 2021.
2. Signifor LAR Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2020. Available at https://www.signiforlar.com/pdf/signifor-lar-pi.pdf. Accessed August 12, 2021.
3. Melmed S, Bronstein MD, Chanson P. A Consensus Statement on acromegaly therapeutic outcomes. Nat Rev Endocrinol. 2018 Sep;14(9):552-561. doi: 10.1038/s41574-018-0058-5. Availble at: https://www.nature.com/articles/s41574-018-0058-5.
4. Katznelson L, Laws ER, Melmed S, et al. Acromegaly: An Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2014; 99(11): 3933-3951.
5. Nieman LK, Biller BMK, Findling JW, et al. Treatment of Cushing's syndrome: An Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2015; 100(8): 2807-

2831. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4525003/?report=printable.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J2502	Injection, pasireotide long acting, 1 mg

Reviews, Revisions, and Approvals	Date	Approval Date
4Q 2018 annual review: Signifor added to policy; criteria added for new FDA indication for Signifor LAR: Cushing's disease; new strengths of Signifor LAR added; requirement for inadequate response to surgery or pituitary irradiation added for acromegaly; references reviewed and updated.	08/18	
4Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	10/30/19	
4Q 2020 annual review: increased acromegaly initial approval duration from 3 months to 6 months to align with approach for other acromegaly policies; references reviewed and updated.	08/20	11/20
4Q 2021 annual review: no significant changes; updated J code; references reviewed and updated	10/2021	