Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 133.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Signifor LAR (pasireotide LAR)

Applicable line of business:

Commercial	X	Medicaid	X
Medicare	X	ACA	X
CHIP	X		

I. Policy:
Signifor LAR (pasireotide LAR)

II. Purpose/Objective:
To provide a policy of coverage regarding Signifor LAR (pasireotide LAR)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Signifor LAR (pasireotide LAR) is a cyclohexapeptide somatostatin analogue which is a peptide inhibitor of multiple endocrine, neuroendocrine, and exocrine mechanisms. In patients with Cushing disease, pasireotide binds to somatostatin receptor (sst_{1-5}), with high affinity for the sst_1, sst_2, sst_3 subtypes, and highest affinity for the sst_5 subtype, resulting in inhibition of ACTH secretion which leads to decreased cortisol secretion. In patients with acromegaly, pasireotide binds to sst_2 and sst_5, resulting in decreased GH and IGF-1.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Signifor LAR (pasireotide LAR) will be considered medically necessary for the commercial, exchange, CHIP, and Medicaid lines of business when all of the following criteria are met:

Acromegaly
- Medical record documentation of a diagnosis of acromegaly **AND**
- Must be prescribed by an endocrinologist **AND**
- Medical record documentation of an inadequate response to or inability to be treated with surgery and/or radiotherapy **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Somatuline depot OR Sandostatin LAR **AND**
- **If the patient also has a diagnosis of diabetes**: there must be medical record documentation of diabetes control demonstrated by documentation that the member has met their personal HbA1c goal.

Cushing's Disease
- Medical record documentation of a diagnosis of Cushing's disease **AND**
- Prescription written by an endocrinologist **AND**
- Medical record documentation that pituitary surgery is not an option or has not been curative **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to ketoconazole AND Metopirone

AUTHORIZATION DURATION
For Acromegaly: Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement in GH and IGF-1 levels on six (6) months of Signifor LAR therapy is required. After the initial six (6) month approval, subsequent approvals will be for a duration of six (6) months, requiring medical record documentation of continued or sustained improvement in signs and symptoms of acromegaly while on Signifor LAR therapy.

For Cushing's Disease: If approved, approval will be given for a period of six (6) months. Re-authorization will require medical record documentation that urinary free cortisol levels are within normal limits.

LIMITATIONS: a quantity limit 1 dose every 28 days should be applied

Signifor LAR (pasireotide LAR) will be considered medically necessary for the Medicare line of business when all of the following criteria are met:

Acromegaly

- Medical record documentation of a diagnosis of acromegaly **AND**
- Must be prescribed by an endocrinologist **AND**
- Medical record documentation of an inadequate response to or inability to be treated with surgery and/or radiotherapy **AND**
- **If the patient also has a diagnosis of diabetes**: there must be medical record documentation of diabetes control demonstrated by documentation that the member has met their personal HbA1c goal.

Cushing's Disease

- Medical record documentation of a diagnosis of Cushing's disease **AND**
- Prescription written by an endocrinologist **AND**
- Medical record documentation that pituitary surgery is not an option or has not been curative

AUTHORIZATION DURATION

For Acromegaly: Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement in GH and IGF-1 levels on six (6) months of Signifor LAR therapy is required. After the initial six (6) month approval, subsequent approvals will be for a duration of six (6) months, requiring medical record documentation of continued or sustained improvement in signs and symptoms of acromegaly while on Signifor LAR therapy.

For Cushing's Disease: If approved, approval will be given for a period of six (6) months. Re-authorization will require medical record documentation that urinary free cortisol levels are within normal limits.

LIMITATIONS: a quantity limit 1 dose every 28 days should be applied

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Signifor LAR [prescribing information]. Lebanon, NJ: Recordati Rare Diseases Inc; July 2024.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 7/21/2015

Revised: 11/20/18 (Cushing's disease), 8/19/22 (Medicaid PARP statement), 8/18/23 (LOB carve out, Medicaid business segment), 12/30/23 (references added), 8/8/24 (Description, LOB table, taglines)

Reviewed: 5/27/16, 5/16/17, 5/1/18, 9/30/19, 8/26/20, 8/20/21, 7/23/25

MA UM Committee approval: 12/31/23, 12/31/24, 9/10/25

DHS PARP approval: 8/14/25