Pasireotide (Signifor® LAR)

Requires Step Therapy See "Step Therapy Requirements for Provider Administered Specialty Medications" Document at: https://www.bcbst.com/docs/providers/Comm_BC_PAD_Step_Therapy_Guide.pdf

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

- Treatment of patients with acromegaly who have had an inadequate response to surgery and/or for whom surgery is not an option.
- Treatment of patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative.

All other indications are considered experimental/investigational and not medically necessary.

DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

Acromegaly:

- For initial approval: Laboratory report indicating high pretreatment insulin-like growth factor-1 (IGF-1) level and chart notes indicating an inadequate or partial response to surgery or that surgery is not an option.
- For continuation: Laboratory report indicating normal current IGF-1 levels or chart notes indicating that the member's IGF-1 level has decreased or normalized since initiation of therapy.

Cushing's Disease:

- For initial requests, pretreatment cortisol level as measured by one of the following tests:
  - Urinary free cortisol (UFC) level
  - Late-night salivary cortisol
  - 1 mg overnight dexamethasone suppression test (DST)
  - Longer, low dose DST (2 mg per day for 48 hours)
- For continuation of therapy (if applicable), laboratory report indicating current cortisol level has decreased from baseline as measured by one of the following tests:
  - Urinary free cortisol (UFC) level
  - Late-night salivary cortisol

- 1 mg overnight dexamethasone suppression test (DST)
- Longer, low dose DST (2 mg per day for 48 hours)

COVERAGE CRITERIA

Acromegaly

Authorization of 12 months may be granted for the treatment of acromegaly when all of the following criteria are met:

- Member has a high pretreatment IGF-1 level for age and/or gender based on the laboratory reference range.
- Member meets one of the following:
  - Member had an inadequate or partial response to surgery.
  - Surgery is not an option for the member.

Cushing's Disease

Authorization of 12 months may be granted for the treatment of Cushing's disease when the member has had surgery that was not curative OR the member is not a candidate for surgery.

CONTINUATION OF THERAPY

Acromegaly

Authorization of 12 months may be granted for continuation of therapy for acromegaly when the member's IGF-1 level has decreased or normalized since initiation of therapy.

Cushing's Disease

Authorization of 12 months for continuation of therapy may be granted for members that meet one of the following criteria:

- Lower cortisol levels since the start of therapy per one of the following tests:
  - Urinary free cortisol (UFC)
  - Late-night salivary cortisol
  - 1 mg overnight dexamethasone suppression test (DST)
  - Longer, low dose DST (2 mg per day for 48 hours)
- Improvement in signs and symptoms of the disease

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex

Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

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2. Katznelson L, Laws ER Jr, Melmed S, et al. Acromegaly: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2014;99:3933-3951.
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4. Gadelha MR, Bronstein MD, Brue T, et al. Pasireotide versus continued treatment with octreotide or lanreotide in patients with inadequately controlled acromegaly (PAOLA): a randomized, phase 3 trial. Lancet Diabetes Endocrinol. 2014;2:875-84.
5. Colao A, Bronstein MD, Freda P, et al. Pasireotide versus octreotide in acromegaly: a head-to-head superiority study. J Clin Endocrinol Metab. 2014;99:791–799.
6. 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):2807-31.
7. 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: 847-875.

EFFECTIVE DATE 7/31/2026

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