Effective Date 12/1/2023
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Coverage Policy Number IP0165

Pasireotide Long-Acting

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for pasireotide (Signifor® LAR) injectable suspension.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Pasireotide (Signifor LAR) injectable suspension is considered medically necessary when ONE of the following is met (1, 2, 3 or 4):

1. **Acromegaly.** Individual meets **ALL** of the following criteria (A, B, C, and D):
    A. Meets **ONE** of the following (i, ii, or iii):
        i. Has had an inadequate response to surgery and/or radiotherapy
        ii. Is NOT an appropriate candidate for surgery and/or radiotherapy

iii. Is experiencing negative effects due to tumor size (for example, optic nerve compression

B. Has (or had) a pre-treatment insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender for the reporting laboratory
C. Medication is prescribed by, or in consultation with, an endocrinologist
D. Meets the preferred covered alternative(s) criteria as indicated in the table below

Dosing for Acromegaly. Up to 60 mg administered intramuscularly no more frequently than every 28 days.

2. **Cushing's Disease.** Individual meets **BOTH** of the following criteria (A and B):
   A. According to the prescriber, is not a candidate for surgery, or surgery has not been curative
   B. Medication is prescribed by, or in consultation with, an endocrinologist or a physician who specializes in the treatment of Cushing's disease

   Dosing for Cushing's Disease. Up to 40 mg administered intramuscularly no more frequently than once every 28 days.

3. **Cushing's Disease/Syndrome – Individual Awaiting Surgery.**
   The medication is prescribed by, or in consultation with, an endocrinologist or a physician who specializes in the treatment of Cushing's disease.

   Dosing for Cushing's Disease/Syndrome – Individual Awaiting Surgery. Up to 40 mg administered intramuscularly no more frequently than once every 28 days.

4. **Cushing's Disease/Syndrome – Individual Awaiting Therapeutic Response After Radiotherapy.**
   The medication is prescribed by, or in consultation with, an endocrinologist or a physician who specializes in the treatment of Cushing's disease.

   Dosing for Cushing's Disease/Syndrome – Individual Awaiting Therapeutic Response After Radiotherapy. Up to 40 mg administered intramuscularly no more frequently than once every 28 days.

Coverage varies across plans and requires the use of preferred products. Refer to the customer's benefit plan document for coverage details.

Employer Group Non-Covered Products and the Preferred Covered Alternatives:

Non-Covered Product	Criteria
Signifor LAR (pasireotide) injectable suspension	For a diagnosis of **Acromegaly** only. There is documentation the individual has had **ONE** of the following (A or B): A. Previously started on or is currently receiving Signifor LAR injectable suspension B. An inadequate response, contraindication, or is intolerant to Somatuline Depot (lanreotide acetate) injection

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Pasireotide (Signifor LAR) injectable suspension is considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration:

- Acromegaly: up to 12 months
- Cushing's Disease: up to 4 months
- Cushing's Disease/Syndrome – Individual Awaiting Surgery: up to 4 months
- Cushing's Disease/Syndrome – Individual Awaiting Therapeutic Response After Radiotherapy: up to 4 months

Reauthorization approval duration:

- Acromegaly: up to 12 months
- Cushing's Disease: up to 12 months
- Cushing's Disease/Syndrome – Individual Awaiting Surgery: not applicable for continuation beyond initial approval duration
- Cushing's Disease/Syndrome – Individual Awaiting Therapeutic Response After Radiotherapy: not applicable for continuation beyond initial approval duration

Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

Coding

1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

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

Background

OVERVIEW

Signifor LAR, a somatostatin analog, is indicated for the following uses:[1]

- **Acromegaly**, in patients who have had an inadequate response to surgery and/or for whom surgery is not an option. In vivo studies show that Signifor LAR lowers growth hormone and insulin-like growth factor-1 levels in patients with acromegaly.
- **Cushing's disease**, in patients for whom pituitary surgery is not an option or has not been curative.

Disease Overview

Cushing's syndrome refers to the general state of excessive levels of cortisol (hypercortisolism) in the blood.[2,3] Hypercortisolism can occur for reasons that are either endogenous or exogenous in nature (e.g., Cushing's disease, cortisol-containing medications, adrenal gland tumor, certain cancers). Cushing's disease (hypercortisolism caused by pituitary adenomas) is the most common type of adrenocorticotropic hormone (ACTH)-dependent Cushing's syndrome. Treatment for Cushing's syndrome requires a multi-modal approach. The goals of treatment are normalization of cortisol excess, long-term disease control, avoidance of recurrence, and reversal of clinical features.[4]

Guidelines

The Endocrine Society published clinical practice guidelines for the treatment of Cushing's syndrome in (2015) and Cushing's disease (2021).[5,6] Recorlev is recognized in the 2021 guidelines for Cushing's disease as

investigational; further details regarding this therapy are not discussed. Treatment goals for Cushing's syndrome are to normalize cortisol levels or its action at the receptors to eliminate signs and symptoms of Cushing's syndrome. Best practice adjunctive management include treating co-morbidities associated with hypercortisolism (psychiatric disorders, diabetes, hypertension, hypokalemia, infections, dyslipidemia, osteoporosis, and poor physical fitness). First-line treatment involves resection of the tumor, unless surgery is not possible or is unlikely to meaningfully reduce excess glucocorticoid. Specifically for Cushing's disease, transsphenoidal selective adenomectomy by a surgeon with extensive experience in pituitary surgery is recommended. In patients with ACTH-dependent Cushing's syndrome who underwent noncurative surgery or for whom surgery was not possible, the guidelines advocate several second-line therapies (e.g., repeat transsphenoidal surgery, radiotherapy, medical therapy, and bilateral adrenalectomy). For Cushing's disease, the guidelines recommend all medical therapies as second-line options after transsphenoidal surgery. These involve steroidogenesis inhibitors (ketoconazole, Metopirone® [metyrapone capsules], Lysodren® [mitotane tablets], etomidate) in patients either with or without radiotherapy/radiosurgery; pituitary-directed medical treatments (cabergoline, Signifor® [pasireotide subcutaneous injection]) in patients who are not surgical candidates or who have persistent disease; and Korlym® (mifepristone tablets) in patients with diabetes or glucose intolerance who are not surgical candidates or who have persistent disease after transsphenoidal surgery.

References

1. Signifor® LAR subcutaneous injection [prescribing information]. Lebanon, NJ: Recordati Rare Diseases; July 2021.
2. Sharma ST, Nieman LK, Feelders RA. Cushing's syndrome: epidemiology and developments in disease management. Clin Epidemiol. 2015;7:281–293.
3. Tritos NA, Biller BM. Advances in medical therapies for Cushing's syndrome. Discov Med. 2012;13(69):171-179.
4. Biller BMK, Grossman AB, Stewart PM, et al. Treatment of adrenocorticotropin-dependent Cushing's syndrome: A consensus statement. J Clin Endocrinol Metab. 2008;93:2454-2462.
5. Nieman LK, Biller BM, Findling JW. Treatment of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2015;100(8):2807-2831.
6. 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(12):847-875.