

PRIOR AUTHORIZATION POLICY

POLICY: Somatostatin Receptor Agonist – Palsonify Prior Authorization Policy

- Palsonify™ (paltusotine tablets – Crinetics)

REVIEW DATE: 10/08/2025

OVERVIEW

Palsonify, a somatostatin receptor agonist, is indicated for the treatment of adults with acromegaly who had an inadequate response to surgery and/or for whom surgery is not an option.¹

GUIDELINES

The current guidelines do not address Palsonify. The Pituitary Society guidelines on acromegaly management (2021) emphasize a personalized approach to medication management, especially for patients who are not surgical candidates or have residual disease post-surgery.² First-line medical therapy includes somatostatin analogs such as octreotide, lanreotide, and Signifor LAR® (pasireotide intramuscular injection), which target GH secretion. Somavert, a GH receptor antagonist, is recommended for patients with persistent insulin-like growth factor 1 (IGF-1) elevation despite somatostatin analog therapy. Dopamine agonists like cabergoline are considered for mild cases or as adjuncts. Newer agents, including Mycapssa and investigational drugs like Palsonify, offer promising alternatives with improved convenience and tolerability. The guidelines stress the importance of tailoring therapy based on biochemical response, tumor characteristics, and patient preferences, with increasing interest in biomarker-guided treatment strategies to optimize outcomes. The Endocrine Society Clinical Practice Guidelines for Acromegaly (2014) recommend medical therapy as adjuvant treatment after surgical intervention. Primary medical therapy with somatostatin analogs (no preferred agent) can be recommended for some patients (e.g., surgery is not curative or patient is a poor surgical candidate).³

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Palsonify. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Palsonify as well as the monitoring required for adverse events and long-term efficacy, approval requires Palsonify to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Palsonify is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Acromegaly.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient meets ONE of the following (i, ii, or iii):
 - i. Patient has had an inadequate response to surgery and/or radiotherapy; OR
 - ii. Patient is NOT an appropriate candidate for surgery and/or radiotherapy; OR
 - iii. Patient is experiencing negative effects due to tumor size (e.g., optic nerve compression); AND

- C) Patient has (or had) a pretreatment (baseline) insulin-like growth factor 1 (IGF-1) level above the upper limit of normal based on age and gender for the reporting laboratory; AND

Note: Pre-treatment (baseline) refers to the IGF-1 level prior to the initiation of any somatostatin analog (e.g., Mycapssa [octreotide delayed-release capsules], an octreotide acetate injection product [e.g., Bynfezia Pen, Sandostatin {generics}, Sandostatin LAR Depot], Signifor LAR [pasireotide injection], Somatuline Depot [lanreotide injection], dopamine agonist [e.g., cabergoline, bromocriptine], or Somavert [pegvisomant injection]). Reference ranges for IGF-1 vary among laboratories.

- D) The medication is prescribed by or in consultation with an endocrinologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Palsonify is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Palsonify™ tablets [prescribing information]. Summit, NJ: San Diego, CA: Crinetics; September 2025.
2. Fleseriu M, Biller BMK, Freda PU, et al. A Pituitary Society update to acromegaly management guidelines. *Pituitary*. 2021;24(1):1-13.
3. Katznelson L, Laws ER Jr, Melmed S, et al; Endocrine Society. Acromegaly: an endocrine society clinical practice guideline. *J Clin Endocrinol Metab*. 2014;99:3933-3951.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	10/08/2025