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Section:	Prescription Drugs	**Effective Date:**	April 1, 2026
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	October 24, 2025
Subject:	Palsonify	**Page:**	1 of 4

Last Review Date: March 6, 2026

Palsonify

Description

Palsonify (paltusotine)

Background
Similar to the natural hormone somatostatin, Palsonify (paltusotine) suppresses growth hormone (GH) and insulin-like growth factor-1 (IGF-1) secretion. Palsonify exerts its pharmacological activity via selective agonism at somatostatin receptor 2 (SSTR2) and exhibits little or no affinity for other SST receptor subtypes. Palsonify inhibited cyclic adenosine monophosphate accumulation via human SSTR2 activation with an average drug (agonist) concentration that results in half-maximal response (EC_{50}) of 0.25 nM (1).

Regulatory Status
FDA-approved indication: Palsonify is a somatostatin receptor agonist indicated for the treatment of adults with acromegaly who have had an inadequate response to surgery and/or for whom surgery is not an option (1).

The recommended initial dosage of Palsonify is 40 mg once daily. After 2 to 4 weeks on Palsonify 40 mg once daily, based on IGF-1 levels, titrate to a dosage of 60 mg once daily. Patients taking concomitant moderate or strong CYP3A4 inducers may require an increased dosage of Palsonify. Palsonify dosage should not exceed three-fold the dosage prior to concomitant use or 120 mg daily, whichever is less (1).

Palsonify has warnings regarding: cholelithiasis; hyperglycemia and hypoglycemia; cardiovascular abnormalities; thyroid function abnormalities; steatorrhea and malabsorption of dietary fats; and Vitamin B_{12} deficiency (1).

The safety and effectiveness of Palsonify in pediatric patients less than 18 years of age have not been established (1).

Related policies
Mycapssa, Sandostatin, Sandostatin LAR, Signifor LAR, Somatuline Depot

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Palsonify may be considered **medically necessary** if the conditions indicated below are met.

Palsonify may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Acromegaly

AND ALL of the following:

a. Patient has had an inadequate treatment response to surgery **OR** surgery is not an option
b. Prescriber agrees to monitor **ALL** of the following:
    i. IGF-1 levels
    ii. Blood glucose
    iii. Thyroid function
    iv. Electrocardiogram (ECG)
    v. Vitamin B_{12} levels

vi. Signs or symptoms of cholelithiasis (gallstones) or associated complications

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Acromegaly

AND the following:

a. Prescriber agrees to monitor **ALL** of the following:
   i. IGF-1 levels
   ii. Blood glucose
   iii. Thyroid function
   iv. Electrocardiogram (ECG)
   v. Vitamin B_{12} levels
   vi. Signs or symptoms of cholelithiasis (gallstones) or associated complications

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 120 mg per day

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary
Palsonify (paltusotine) suppresses growth hormone (GH) and insulin-like growth factor-1 (IGF-1) secretion. It is a somatostatin receptor agonist indicated for the treatment of adults with acromegaly who have had an inadequate response to surgery and/or for whom surgery is not an option. The safety and effectiveness of Palsonify in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Palsonify while maintaining optimal therapeutic outcomes.

References

1. Palsonify [package insert]. San Diego, CA: Crinetics Pharmaceuticals, Inc.; September 2025.

Policy History

Date	Action
October 2025	Addition to PA
March 2026	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 6, 2026 and is effective on April 1, 2026.