Clinical Policy: Paltusotine (Palsonify)

Reference Number: PA.CP.PHAR.755
Effective Date: 02/2026
Last Review Date: 01/2026

Description
Paltusotine (Palsonify™) is a somatostatin receptor agonist.

FDA Approved Indication(s)
Palsonify 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.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Palsonify is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Acromegaly (must meet all)**:**

1. Diagnosis of acromegaly as evidenced by one of the following (a or b):
   a. Pre-treatment insulin-like growth factor-I (IGF-I) level above the upper limit of normal based on age and gender for the reporting laboratory;
   b. Serum growth hormone (GH) level ≥ 1 µg/L after a 2-hour oral glucose tolerance test;
2. Prescribed by or in consultation with an endocrinologist;
3. Age ≥ 18 years;
4. Inadequate response to surgical resection or pituitary irradiation (*see Appendix D*), or member is not a candidate for such treatment;
5. Failure of Mycapssa®^, unless contraindicated or clinically adverse effects are experienced;
   ^Prior authorization may be required for Mycapssa
6. Failure of one of the following^, unless clinically adverse effects are experienced or all are contraindicated (a or b):
   a. Lanreotide (Somatuline® Depot);
   b. Both of the following (i and ii):
      i. Generic octreotide acetate LAR (generic Sandostatin® LAR Depot), unless generic octreotide acetate LAR is unavailable due to shortage;
      ii. If member is unable to use generic octreotide acetate LAR (generic Sandostatin LAR Depot) due to shortage: Sandostatin LAR Depot;

   ^Prior authorization may be required for lanreotide, generic octreotide acetate LAR, and Sandostatin LAR Depot
7. Dose does not exceed both of the following (a and b):
   a. 60 mg per day;
   b. 2 tablets per day.

Approval duration: 12 months

B. Other diagnoses/indications
1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Acromegaly (must meet all)**:**
1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies;
2. Member is responding positively to therapy (*see Appendix D*);
3. If request is for a dose increase, new dose does not exceed both of the following (a and b):
   a. 60 mg per day;
   b. 2 tablets per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
GH: growth hormone
IGF-I: insulin-like growth factor

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
octreotide acetate (Mycapssa) (PO)	20-40 mg PO BID	80 mg/day
octreotide acetate (Sandostatin LAR Depot) (IM)	20-40 mg IM every 4 weeks	See dosing regimen

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
lanreotide acetate (Somatuline Depot)	90-20 mg SC every 4 weeks	See dosing regimen

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
None reported

Appendix D: General Information

- Response to acromegaly therapy (e.g., somatostatin analogs, surgical resection, pituitary irradiation) may include:
  - Improved GH or IGF-I serum concentrations
  - Improved tumor mass control

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Acromegaly	Initial: 40 mg PO QD* During the initiation period, may be temporarily reduced to 20 mg PO QD if needed, based on tolerability. Once adverse reactions have resolved, resume 40 mg PO QD. Maintenance: After 2 to 4 weeks of Palsonify 40 mg PO QD, based on IGF-1 levels, titrate to a dosage of 60 mg PO QD.	60 mg/day

VI. Product Availability

Tablets: 20 mg, 30 mg

VII. References

1. Palsonify Prescribing Information. San Diego, CA: Crinetics Pharmaceuticals; September 2025. Available at: https://crinetics.com/PALSONIFY_pi/. Accessed October 1, 2025.
2. Katznelson L, Laws Jr. ER, Melmed S, et al. Acromegaly: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2014;99:3933-3951.
3. Melmed S, Bronstein MD, Chanson P. A Consensus Statement on acromegaly therapeutic outcomes. Nat Rev Endocrinol. 2018 Sep;14(9):552-561. doi: 10.1038/s41574-018-0058-5.
4. Fleseriu M, Biller BMK, Freda PU, et al. A Pituitary Society update to acromegaly management guidelines. Pituitary. 2021; 24: 1-13.
5. Guistina A, Barkhoudarian G, Beckers A, et al. Multidisciplinary management of acromegaly: A consensus. Rev Endocr Metab Disord. 2020; 21(4): 667-678.
6. Giustina A, Biermasz N, Casanueva FF, et al; Acromegaly Consensus Group (ACG). Consensus on criteria for acromegaly diagnosis and remission. Pituitary. 2024 Feb;27(1):7-22. doi: 10.1007/s11102-023-01360-1.

Reviews, Revisions, and Approvals	Date
Policy created	01/2026