Effective Date: 03/04/2026
Current Effective Date: 03/04/2026
Last P&T Approval/Version: 01/28/2026
Next Review Due By: 07/2026
Policy Number: C30295-A

Palsonify (paltusotine)

PRODUCTS AFFECTED

Palsonify (paltusotine)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Acromegaly

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

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A. ACROMEGALY:
1. Documented diagnosis of acromegaly
   AND
2. Documentation that member is not eligible for pituitary surgery or has had an inadequate response to pituitary surgery or radiation
   AND
3. Documentation of trial and failure, serious side effects, or contraindication to cabergoline at maximally tolerated doses for members with modest elevation (less than 1.4 mcg/L) of insulin-like growth factor-1 (IGF-1) and mild signs and symptoms of growth hormone (GH) excess
   AND
4. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal
   AND
5. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or serious side effects to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s).

CONTINUATION OF THERAPY:

A. ACROMEGALY:
1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
3. Documentation of positive clinical response as demonstrated by reduction of IGF-1 levels (i.e., IGF-1 ≤1.0×ULN) and/or improvements in the condition's signs and symptoms

DURATION OF APPROVAL:

Initial authorization: 12 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a board-certified endocrinologist [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

18 years of age and older

QUANTITY:

40mg once daily, may be titrated to 60mg once daily after 2 to 4 weeks based on IGF-1 levels

PLACE OF ADMINISTRATION:

The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

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DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
Somatostatin Agents

FDA-APPROVED USES:
Indicated for the treatment of adults with acromegaly who had an inadequate response to surgery and/or for whom surgery is not an option

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Acromegaly is a rare condition caused by excess growth hormone (GH), usually from a benign pituitary adenoma. The resulting rise in GH and insulin-like growth factor-1 (IGF-1) disrupts normal physiology and leads to gradual enlargement of the hands, feet, face, and other tissues.

Because acromegaly increases morbidity and mortality, all patients require treatment. Therapy aims to lower GH and IGF-1 levels, shrink or control the tumor, relieve symptoms, and reverse metabolic complications. Transsphenoidal surgery to remove the pituitary tumor is the first-line treatment and often provides rapid improvement, though it is less effective for large tumors. Hormone testing and imaging are typically repeated 12 weeks after surgery to assess for residual disease. If surgery is not possible or symptoms persist, medical therapy is used, and radiation can be added to further reduce tumor size and GH levels.

Palsonify (paltusotine) is a once-daily oral SRA approved for adults with acromegaly who do not respond adequately to surgery or cannot undergo surgery. The FDA-approval included two Phase 3, double-blind, placebo-controlled trials: a 36-week study in patients previously controlled on SSA/SRL (PATHFNDR-1) and a 24-week study in medically naïve, previously treated, or washed-out patients (PATHFNDR-2). In both trials, Palsonify showed markedly superior efficacy compared with placebo, with far more patients achieving IGF-1 levels ≤ ULN (83.3% vs 3.6% in PATHFNDR-1; 56% vs 5% in PATHFNDR-2). Palsonify also produced significant reductions in mean IGF-1, greater symptom improvement, and higher rates of GH <1.0 ng/mL. Additionally, far fewer patients treated with Palsonify required rescue therapy compared with placebo.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Palsonify (paltusotine) are considered experimental/investigational and therefore will follow Molina's Off-Label policy. Contraindications to Palsonify (paltusotine) include: no labeled contraindications.

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Exclusions/Discontinuation:
None

OTHER SPECIAL CONSIDERATIONS:
Take orally once daily with water on an empty stomach (at least 6 hours after a meal) and at least 1 hour before the next meal. Recommended initial dosage is 40 mg once daily. During initiation, Palsonify may be temporarily reduced to 20 mg once daily if needed, based on tolerability. Once adverse reactions have resolved, resume Palsonify 40 mg once daily. After 2 to 4 weeks, based on IGF-1 levels, titrate to 60 mg once daily.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Palsonify TABS 20MG
Palsonify TABS 30MG

REFERENCES

1. Palsonify (paltusotine) tablets [prescribing information]. San Diego, CA: Crinetics Pharmaceuticals, Inc.; September 2025.
2. Katznelson L et al. Acromegaly: an endocrine society clinical practice guideline. JClinEndocrinol Metab. 2014 Nov;99(11):3933-51. Epub 2014 Oct 30.
3. Gadelha, M. R., Luiz Eduardo Wildemberg, Marques, N. V., & Kasuki, L. (2025). Medical Treatment of Acromegaly: Navigating the Present, Shaping the Future. Endocrine Reviews. https://doi.org/10.1210/endrev/bnaf020
4. Broder MS, et al. Incidence and prevalence of acromegaly in the United States: a claims-based analysis. Endocr Pract. 2016;22(11):1327-1335.

SUMMARY OF REVIEW/REVISIONS	DATE
NEW CRITERIA CREATION	Q1 2026

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