

DRUG POLICY

Palsonify® (paltusotine)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

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

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

1. For initial approval: Laboratory report indicating high pretreatment insulin-like growth factor-1 (IGF-1) level and chart notes indicating an inadequate or partial response to surgery or a clinical reason for not having surgery.
2. For continuation: Laboratory report indicating normal current IGF-1 levels or chart notes indicating that the member's IGF-1 level has decreased or normalized since initiation of therapy

Criteria for Initial Approval

Acromegaly

1. Palsonify (paltusotine tablet) may be considered medically necessary for the treatment of acromegaly when all of the following criteria are met:
 - A. Member is 18 years of age or older

- B. Member has a high pretreatment IGF-1 level for age and/or gender based on the laboratory reference range
- C. Member has a confirmed diagnosis of acromegaly
- D. Member had an inadequate or partial response to surgery (i.e., unable to achieve normalization of IGF-I levels) OR there is a clinical reason why the member has not had surgery
- E. Member has had a documented inadequate response, intolerable adverse effect, or contraindication to BOTH Sandostatin LAR (octreotide) injection AND Somatuline Depot (lanreotide) injection
- F. Member has had a documented inadequate response, intolerable adverse effect, or contraindication to self-administered immediate-release octreotide injection (e.g., generic Sandostatin)

Approval will be for 6 months

Continuation of Therapy

Acromegaly

1. Continued treatment with Palsonify (paltusotine tablet) may be considered medically necessary for the treatment of acromegaly when the following criteria are met:
 - A. The member has experienced a positive clinical response to Palsonify therapy as demonstrated by all of the following:
 - i. No evidence of disease progression
 - ii. Documented reduction of normalization of IGF-1 level since initiating therapy

Approval will be for 12 months

Other

Palsonify (paltusotine tablet) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.

Non-Formulary Exception Criteria

Non-Formulary Exception criteria applies to formularies which do not include the requested product(s) on the formulary drug list. Meeting the criteria above may satisfy some, or all, portions of the Non-Formulary Exception Criteria. A medication that is non-formulary may be covered when the Criteria for Approval AND the following criteria are met:

1. The requested drug must be used for an FDA-approved indication, or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines). Diagnostic testing/lab results required when applicable.
2. The prescribed dose/quantity must fall within the FDA-approved labeling or dosing guidelines found in the compendia of current literature.
3. All covered formulary alternative drugs on any tier will be ineffective, have been ineffective, would not be as effective as the non-formulary drug, or would have adverse effects. Documentation is required and must include chart note(s) or other documentation indicating prior treatment failure, severity of the adverse event (if any), and dosage and duration of the prior treatment, or contraindication to formulary alternatives.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

Medication	Standard Limit	FDA Recommended Dosing
Palsonify (paltusotine)20 mg tablet	60 tablets per 30 days	Initial dosage 40mg orally once daily. After 2 to 4 weeks on 40 mg once daily, may increase to 60 mg once daily based on IGF-1 levels.
Palsonify (paltusotine)30 mg tablet	60 tablets per 30 days	

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- N/A

REFERENCES

- Palsonify [package insert]. San Diego, CA: Crinetics Pharmaceuticals, Inc.; September 2025.
- Katznelson L, Laws ER, Melmed S, et al. Acromegaly: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2014; 99:3933-3951.
- American Association of Clinical Endocrinologists Acromegaly Guidelines Task Force. Medical guidelines for clinical practice for the diagnosis and treatment of acromegaly – 2011 update. Endocr Pract. 2011; 17(suppl 4):1-44.

POLICY HISTORY

Policy #: 05.06.12

Original Effective Date: March 5, 2026

Reviewed:

Revised:

Current Effective Date: March 5, 2026