

Palsonify (Paltusotine)

POLICY

I. INDICATIONS

FDA-Approved Indications

Palsonify is indicated for the treatment of adults with acromegaly who have had an inadequate response to surgery and/or surgery for whom surgery is not an option.

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

A. Acromegaly

Authorization of 6 months may be granted for the treatment of acromegaly when all of the following criteria are met:

1. The requested drug is prescribed by or in consultation with an endocrinologist
2. Documentation that the diagnosis of acromegaly has been confirmed by one of the following:
 - a. Serum GH level > 1 ng/ml after 2-hour OGTT at time of diagnosis; OR
 - b. Elevated serum insulin-like growth factor-1 (IGF-1) [above the age and gender adjusted normal range per physician's lab] at diagnosis
3. Documentation that the member has a recent high pretreatment insulin-like growth factor-1 (IGF-1) level for age and/or gender based on the laboratory reference range.
4. Documentation that the member had an inadequate or partial response to surgery OR there is a clinical reason why the member has not had surgery
5. Documentation that Palsonify will not be taken concomitantly with a strong or moderate CYP3A4 inducer.
6. Documentation that the member has had an inadequate treatment response, intolerance or contraindication to Somatuline Depot (lanreotide acetate) OR Sandostatin LAR Depot (octreotide acetate)

III. CONTINUATION OF THERAPY

A. Acromegaly

Authorization of 6 months may be granted for continuation of therapy for acromegaly when documentation is provided that the member's IGF-1 level has decreased or normalized since initiation of therapy.

IV. QUANTITY LIMIT

- Palsonify 20mg or 30mg tablets: two tablets per day

V. REFERENCES

1. Palsonify [package insert]. San Diego, CA: Crinetics Pharmaceuticals, Inc.; September 2025.
2. Katznelson L, Laws ER, Melmed S, et al. Acromegaly: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2014; 99:3933-3951.
3. 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.