PHARMACY POLICY STATEMENT
Ohio Medicaid

DRUG NAME	Palsonify (paltusotine)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Palsonify, approved by the FDA in 2025, is a somatostatin receptor agonist indicated for the treatment of adults with acromegaly who had an inadequate response to surgery and/or for whom surgery is not an option. Acromegaly is typically the result of a GH-secreting pituitary adenoma, thus surgical resection is the preferred treatment whenever possible as the best chance for a cure.

Palsonify (paltusotine) will be considered for coverage when the following criteria are met:

Acromegaly

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with an endocrinologist; AND
3. Member has a diagnosis of acromegaly confirmed by insulin-like growth factor (IGF-1) elevation above normal; AND
4. Documentation of an inadequate response to surgery or surgery is not an option; AND
5. **Dosage allowed/Quantity limit:** administer initial dose of 40 mg once daily. After 2 to 4 weeks, based on IGF-1 levels, titrate to 60 mg once daily. Quantity limit: 60 tablets per 30 days.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must demonstrate normalized or improved (decreased) IGF-1.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Palsonify (paltusotine) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
10/15/2025	New policy for Palsonify created. ODM approved on 01/28/26.

References:

1. Palsonify [prescribing information]. Crinetics Pharmaceuticals, Inc.; 2025.
2. Fleseriu M, Biller BMK, Freda PU, et al. A Pituitary Society update to acromegaly management guidelines. *Pituitary*. 2021;24(1):1-13. doi:10.1007/s11102-020-01091-7

3. Katznelson L, Laws ER Jr, Melmed S, et al. Acromegaly: an endocrine society clinical practice guideline. *J Clin Endocrinol Metab*. 2014;99(11):3933-3951. doi:10.1210/jc.2014-2700
4. Fleseriu M, Langlois F, Lim DST, Varlamov EV, Melmed S. Acromegaly: pathogenesis, diagnosis, and management. *Lancet Diabetes Endocrinol*. 2022;10(11):804-826. doi:10.1016/S2213-8587(22)00244-3
5. Ohio Administrative Code. (2022, February 23). 5160-1-01 (C) Medicaid medical necessity: definitions and principles. Retrieved February 22 2023 from codes.ohio.gov.
6. Ohio Administrative Code. (2022, July 18). 5160-26-03 Managed care: covered services. Retrieved February 22, 2023 from codes.ohio.gov.
7. Ohio Administrative Code. (2020, January 1). 5160-9-03 Pharmacy services: covered drugs and associated limitations. Retrieved February 22, 2023 from codes.ohio.gov.

Effective date: 04/01/2026
Revised date: 10/15/2025