UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2026 P 2395-1
Program	Prior Authorization/Medical Necessity
Medication	Palsonify™ (paltusotine)*
P&T Approval Date	3/2026
Effective Date	6/1/2026

1. Background:

Palsonify (paltusotine)* 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.

2. Coverage Criteria [a]:

A. Initial Authorization

1. **Palsonify*** will be approved based on **all** of the following criteria:

   a. Diagnosis of acromegaly

   -AND-

   b. Patient is ≥ 18 years old

   -AND-

   c. Diagnosis confirmed by **one** of the following:

      (1) Serum growth hormone (GH) level > 1 ng/mL after a 2-hour oral glucose tolerance test (OGTT) at time of diagnosis

      -OR-

      (2) Elevated serum insulin-like growth factor 1 (IGF-1) levels (above the age and gender adjusted normal range as provided by the provider's lab) at time of diagnosis

   -AND-

   d. **One** of the following:

      (1) Inadequate response to surgery

      -OR-

      (2) Patient is not a candidate for surgery

-AND-

e. Prescribed by or in consultation with an endocrinologist

Authorization will be issued for 12 months.

B. Reauthorization

1. **Palsonify*** will be approved based on the following criterion:

   a. Documentation of positive clinical response to Palsonify therapy (e.g., age-normalized serum IGF-1 level)

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

*Palsonify is typically excluded from coverage. Tried/Failed criteria may be in place. Please refer to plan specifics to determine exclusion status.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Palsonify [package insert]. San Diego, CA: Crinetics Pharmaceuticals, Inc.; September 2025.
2. 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.
3. Fleseriu M, Biller BMK, Freda PU, et al. A Pituitary Society update to acromegaly management guidelines. *Pituitary*. 2021;24(1):1-13.

Program	Prior Authorization/Medical Necessity - Palsonify™ (paltusotine)
Change Control	
3/2026	New program