PALSONIFY™ (paltusotine) Sample Letter of Medical Necessity Template

This sample letter of medical necessity template is provided as a guidance tool to support your patient undergoing treatment with PALSONIFY. As a healthcare provider, you are expected to evaluate your patient's specific medical needs and update the content accordingly based on your clinical judgment. Crinetics does not assume liability for any outcomes resulting from the use of this sample letter of medical necessity template.

Crinetics Pharmaceuticals

Once-Daily Oral Palsonify™ (paltusotine) tablets

©2025 Crinetics Pharmaceuticals, Inc. All rights reserved.
US-PAL-2500077-1 09/2025

Sample Letter of Medical Necessity for PALSONIFY™ (paltusotine)

[Physician's letterhead]

Attention: Claims Department
[Date]
[Health plan contact]
[Health plan name]
[Health plan street address]
[Health plan city, state ZIP]

RE: Letter of Medical Necessity for Once-Daily Oral PALSONIFY™ (paltusotine)

[Insured patient name]
Date of birth: [patient date of birth]
Policy number: [Policy #]
Group number: [Group #]
Claim number: [Claim # (if known)]

To whom it may concern,

My name is [name, medical specialty (NPI)], and I am writing this letter on behalf of my patient, [patient full name, ID #, Group #], to request approval for treatment with PALSONIFY. [Patient name] has been under my care for the diagnosis associated with E22.0, acromegaly, since [month day, year].

Based on my clinical judgment, PALSONIFY is a medically necessary treatment for [patient name]. [Patient name] is [a/an age]-year-old [male/female] patient who has been diagnosed with acromegaly since [month year]. [Describe patient's condition; if applicable, include details such as persistent or recurrent disease despite pituitary gland surgery and whether or not the patient is a candidate for pituitary gland surgery, and accurately document the patient's response to past treatments.]

With PALSONIFY treatment, [describe your professional opinion of your patient's disease progression and rationale for the currently prescribed product].

My current treatment plan for [patient name] includes [acromegaly therapy] at [dosage, frequency]. [Patient name] has been on this treatment plan since [date]. [Include information on the progress of current treatment plan and reason(s) for discontinuation or contraindications/ineligibility for specific treatments.] [If applicable to the patient's history, include any increased frequency of injections and/or combination therapy.]

Rationale for PALSONIFY:

- If the patient is not a candidate for surgery:
  [My patient is deemed ineligible for a surgical procedure due to being too high risk (eg, severe pharyngeal thickness and sleep apnea or high-output heart failure) OR my patient is not a surgical candidate as the tumor is unresectable OR my patient has recurrent disease after initial surgical management and does not qualify for repeat surgery.]
- Clinical efficacy and safety profile:
  [detailed rationale summarizing clinical trial results relevant to the patient's diagnosis]
  - [For patients switching from injected octreotide or lanreotide] PATHFNDR-1 full trial data [available upon request or in the enclosed literature]
  - For untreated patients] PATHFNDR-2 full trial data [available upon request or in the enclosed literature]
- Most appropriate therapy:
  [detailed rationale specifying why current acromegaly therapies are not effective for the patient, including, if applicable, patient is biochemically controlled or patient is not biochemically uncontrolled, meaning their IGF levels >1.3 ULN; acromegaly symptoms (eg, experiencing headaches, joint pain); quality of life concerns or impact on quality of life; potential adverse events; contraindications in this specific patient; previous trials and failures; and reasons for discontinuation]

Please promptly review the enclosed information to authorize PALSONIFY treatment for [patient name]. My office can be contacted at [phone number] or [email address] if additional information is required to approve this request. Thank you in advance for your timely attention to this matter.

Sincerely,
[Physician name, medical specialty, NPI]
[Physician address]
[Physician phone number]
[Physician fax number]

Enclosures [suggested]:
[Relevant patient medical records]
[PALSONIFY Prescribing Information]
[Relevant literature (eg, Phase III PATHFNDR-1 and/or PATHFNDR-2 clinical trial data)]

Reference: ICD10Data.com. Acromegaly and pituitary gigantism. Accessed July 18, 2025. https://www.icd10data.com/ICD10CM/Codes/E00-E89/E20-E35/E22-/E22.0