Once-Daily Oral

Palsonify™

(paltusotine) tablets

Access and reimbursement guide for healthcare providers (HCPs)

Access, simplified: Practical support to help your patients with acromegaly start—and stay on—PALSONIFY

INDICATION:

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.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS:

- **Cholelithiasis and Its Complications:** Cholelithiasis, including related complications such as acute cholecystitis and pancreatitis, have been reported. Monitor patients periodically. Discontinue PALSONIFY if complications of cholelithiasis occur and treat appropriately.

Please see additional Important Safety Information on pages 14-15 and Full Prescribing Information including Patient Information.

Crinetics Pharmaceuticals

Table of contents

ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; NDC=National Drug Code.

Your Crinetics field reimbursement liaison (FRL) is here to help navigate patient access to PALSONIFY

Please contact your **Crinetics FRL** if you have any questions about the information contained in this guide or call CrinetiCARE® at **1-844-CRN-HELP** (1-844-276-4357).

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS: (cont'd)

- **Hyperglycemia and Hypoglycemia:** Hyperglycemia, diabetes mellitus, or hypoglycemia, may occur. Monitor blood glucose levels when PALSONIFY treatment is initiated or when dosage is altered. Adjust antidiabetic treatment accordingly.
- **Cardiovascular Abnormalities:** Cardiac conduction abnormalities and other ECG changes such as PR interval prolongation, bradycardia, sinus arrest, and atrioventricular block may occur in patients with acromegaly and were reported in PALSONIFY clinical trials. Dosage adjustments of concomitant drugs that have bradycardic effects may be necessary.

About this guide

Support for navigating complexities with PA requests and other potential challenges to access is available with CrinetiCARE.

This resource has been created to provide guidance and tips for successful claims, including resources to support each step of the reimbursement process.

In addition, our personalized CrinetiCARE program may help you navigate your patient's journey with PALSONIFY.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS: (cont'd)

- **Thyroid Function Abnormalities:** Somatostatin analogs may suppress the secretion of thyroid-stimulating hormone, which may result in hypothyroidism. Periodic assessment of thyroid function is recommended.
- **Steatorrhea and Malabsorption of Dietary Fats:** Somatostatin analog treatment may result in malabsorption of dietary fats and subsequent symptoms of steatorrhea, loose stools, abdominal bloating, and weight loss. If new or worsening symptoms are reported with PALSONIFY, evaluate patients for potential pancreatic exocrine insufficiency and manage accordingly.
- **Vitamin B_{12} Deficiency:** Vitamin B_{12} deficiency may occur. Monitor vitamin B_{12} levels, if clinically indicated.

Coverage, coding, and reimbursement support

CrinetiCARE®

CrinetiCARE offers personalized support to help your eligible patients throughout their treatment journey with PALSONIFY.

CrinetiCARE provides access and reimbursement support to help patients start and stay on therapy with PALSONIFY. From navigating insurance coverage to connecting with nurse educators, CrinetiCARE is here to support access for your patients.

- Benefits investigation
- Prior authorization support
- Appeals support

Financial support*

Patient assistance program: Eligible uninsured or underinsured patients may be able to receive PALSONIFY at no cost.

Copay assistance program: Eligible commercially insured patients who are not insured by any federal or government-funded program may pay as little as $0 for PALSONIFY, with up to $25,000 in annual support.

Quick start supply*

Patients who experience a delay in their insurance coverage determination can begin therapy while the CrinetiCARE team works on securing insurance coverage.

Nurse educators

Dedicated nurses are available to provide ongoing education; help answer common questions about therapy; and provide consistent, ongoing support throughout your patient's journey with PALSONIFY.

Contact us

844-CRN-HELP (844-276-4357)

844-CRN-FAXX (844-276-3299)

*For more information about CrinetiCARE programs, please call 844-CRN-HELP (844-276-4357).

Getting started: Prescriptions and navigating insurance coverage

There are 2 ways to generate a prescription for PALSONIFY:

- Via the product enrollment form for PALSONIFY
- Via a prescription sent directly to one of the PALSONIFY pharmacy network partners

As you generate a prescription, it's important to include dosing details that align to the Prescribing Information (PI) for PALSONIFY.

Steps to navigating insurance coverage

1. Clinical decision to prescribe PALSONIFY
2. Fill out PALSONIFY enrollment form and send to the CrinetiCARE HUB
3. CrinetiCARE HUB verifies insurance benefits and sends enrollment form to in-network specialty pharmacy (SP)
4. SP or CrinetiCARE aids in initiating PA
5. Provider submits PA

Visit crineticare.com/hcp to access sample letters of appeal and medical necessity templates. Any letter of appeal or medical necessity form you submit must be based on your assessment of the patient and their individual medical needs.

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS:

Most common adverse reactions (>5%) are diarrhea, abdominal pain, nausea, decreased appetite, sinus bradycardia, hyperglycemia, palpitations, and gastroenteritis.

Sample PA criteria

PAs are used by payers to align treatment access with formulary guidelines and ensure patients receive appropriate therapy.[1]

Seven common reasons PA requests are denied[2]:

1. Cost management
2. Questions regarding medical necessity
3. Administrative errors
4. Procedural errors
5. Requested therapy requires multiple PA requests
6. Patient hasn't tried and failed other medications
7. Prescribed medications are non-formulary

Our FRLs are here to help you and your patients navigate access issues. Visit crineticare.com/hcp for support

IMPORTANT SAFETY INFORMATION (cont'd)

DRUG INTERACTIONS:

- Strong or Moderate CYP3A4 Inducers: may decrease PALSONIFY exposure. May require an increased dosage of PALSONIFY.
- Proton Pump Inhibitors: may decrease PALSONIFY exposure. May require an increased dosage of PALSONIFY. Avoid concomitant use of proton pump inhibitors in patients who are already on PALSONIFY 60 mg.

Sample PA criteria (cont'd)

Before initiating a PA, it is best practice to have the appropriate documentation available for your patient, including lab values, treatment history, and known contraindications.

Please see below on what a PALSONIFY PA submission may include. Example inclusion of copy in brackets will require you to evaluate your patient's specific medical needs and update the content accordingly based on your clinical judgment.

For initial authorization:

Diagnosis:
ICD-10-CM code: E22.0 for acromegaly

Documentation of GH or IGF-1 levels:
Document the patient's GH or IGF-1 levels and date collected prior to and during treatment with any acromegaly therapy
Documentation of inadequate response to previous procedures used or reasons they were not a candidate for such procedures, such as:
Surgical resection
Pituitary irradiation
Bromocriptine mesylate at maximally tolerated dose
Documentation of prior therapies the patient has used, such as:
Cabergoline (generics available)
Dostinex® (cabergoline)
Lanreotide (generics available)
Somatuline® Depot (lanreotide)
Octreotide acetate
MYCAPSSA® (octreotide)
Sandostatin® (octreotide acetate)
Sandostatin® LAR Depot (octreotide acetate)
Signifor® (pasireotide)
Signifor® LAR (pasireotide)
SOMAVERT® (pegvisomant for injection)

Summary of your independent medical judgment as to why PALSONIFY is the appropriate treatment for this patient:

- Patient has tried and failed [other acromegaly therapy]
- Patient not a good candidate for [surgery] and/or [other acromegaly therapy] due to [adverse events or comorbidities]
- Patient has a contraindication to [other acromegaly therapy]
- Increased frequency of injections and/or combination therapy

GH=growth hormone; IGF-1=insulin-like growth factor 1.

Sample PA criteria (cont'd)

For initial authorization (cont'd):

Documentation of contraindication(s) (if applicable):

- Patient has a contraindication to [any acromegaly therapy]

Supporting attachments:

- Attaching chart notes/lab results is considered best practice and can be done electronically

For reauthorization:

Documentation of positive clinical response(s), such as:

- Reduced IGF-1 levels
- Reduced GH levels
- Reduction in symptoms

Quantity limits

Payers may put in quantity limits for how many tablets a patient may receive per day. When submitting for authorization, be sure to include the target dosage for the patient.

Sample quantity limits

Dose	Quantity limit per day
40 mg	2×20 mg tab
60 mg	2×30 mg tab

Recommended Dosage, Titration and Monitoring[3]

- The recommended initial dosage of PALSONIFY is 40 mg once daily
- During initiation period, PALSONIFY may be temporarily reduced to 20 mg once daily if needed, based on tolerability. Once adverse reactions have resolved, resume PALSONIFY 40 mg once daily
- After 2 to 4 weeks on PALSONIFY 40 mg once daily, based on IGF-1 levels, titrate to a PALSONIFY dosage of 60 mg once daily

IMPORTANT SAFETY INFORMATION (cont'd)

DRUG INTERACTIONS: (cont'd)

- Cyclosporine: may decrease cyclosporine exposure. May require cyclosporine dosage adjustment when used with PALSONIFY; follow therapeutic monitoring recommendations.

Example from CoverMyMeds®

Prior authorization, automated

CoverMyMeds streamlines the PA process for providers and pharmacists, offering a process to electronically submit PA requests to every health plan through an online platform and 500+ integrated electronic health record (EHR) systems.

Submit requests for any medication to all plans

Automatically renew previously submitted PA requests

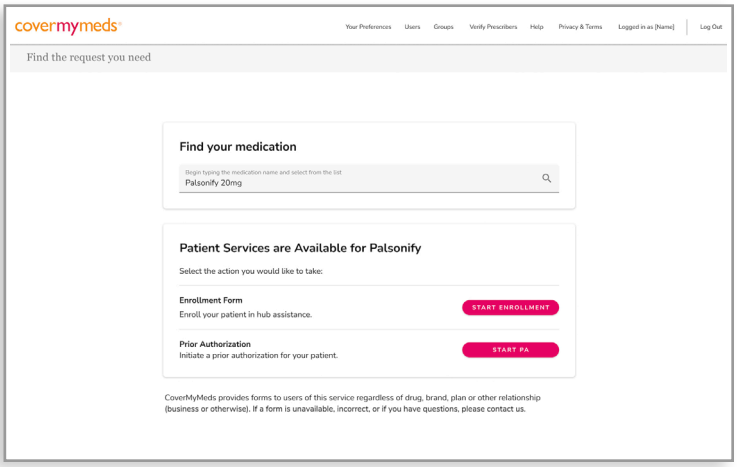
Receive PA determinations, often in real time

Get started in 3 easy steps

1. Create an account with CoverMyMeds or log in to your existing account at covermymeds.com
2. Streamline processes by creating a PA request required for treatment or complete a pharmacy-initiated request
3. Fill in medical details and then click 1 button to electronically submit the request to any plan for determination

CoverMyMeds portal dashboard

Once logged in to the CoverMyMeds portal, you will have access to your personal dashboard, which will serve as a guide to create, search, and manage current PA requests. There is also access to live chat with a CoverMyMeds support team member if help is needed.



Example from CoverMyMeds® (cont'd)

Attaching documentation

Often when completing a PA request, documentation is required with the submission. Below are details to help when documentation is required.

Only 1 document can be attached to the form

If a plan requires additional documentation, all supporting documents must be combined into a single document no larger than 5 MB

Alternately, additional documentation may be faxed to CoverMyMeds

1. Fax the PA, then use the chat feature to notify CoverMyMeds that additional documentation will be faxed
2. Provide the key for the PA and tell CoverMyMeds the number of pages that will be faxed
3. Write the key and number of pages on the top of the first page (cover sheet is not required) and fax to 1-888-965-1415
4. Verify documents are attached by refreshing browser and clicking print/download on the left side of the screen to see all documents
5. Click "Send to Plan" button

Live chat: covermymeds.com
Phone: 1-866-452-5017

Monday–Friday: 8am to 11pm ET
Saturday: 8am to 6pm ET

Resources: go.covermymeds.com/help

Distribution information

Specialty pharmacies supporting PALSONIFY:

- Biologics by McKesson (800-850-4306)
- Orsini Specialty Pharmacy (847-239-5680)

Specialty distributors supporting PALSONIFY:

- McKesson Specialty Health (800-482-6700)
- McKesson Plasma Biologics (877-625-2566)

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Relevant billing codes for PALSONIFY[3,4]

The billing codes listed below may be appropriate when processing billing for PALSONIFY for the treatment of acromegaly.[3]

NDC codes

NDC code	Description
84015-920-60	20 mg tablets
84015-930-60	30 mg tablets

ICD-10-CM[4]

ICD-10-CM codes must be included in all hospital and physician office claims to describe the patient's diagnosis. Consider referencing a current ICD-10-CM manual to select the most appropriate diagnosis code(s) for your patient's condition. The ICD-10-CM diagnosis code listed below is an example of a potentially relevant code for acromegaly.

E22.0 - Acromegaly and pituitary gigantism

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Please report adverse events to Crinetics Pharmaceuticals at 1-833-CRN-INFO (1-833-276-4636) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see Full Prescribing Information including Patient Information.

Learn more at palsonifyhcp.com

References: 1. Academy of Managed Care Pharmacy. Prior authorization. Accessed July 22, 2025. https://www.amcp.org/concepts-managed-care-pharmacy/prior-authorization **2.** CoverMyMeds. 7 common prior authorization hurdles and how to overcome them. December 3, 2024. Accessed July 22, 2025. https://insights.covermymeds.com/healthcare-technology/prior-authorization/common-prior-authorization-hurdles-and-how-to-overcome-them **3.** PALSONIFY. Prescribing information 09/2025. Crinetics Pharmaceuticals, Inc; 2025. **4.** ICD10Data.com. Acromegaly and pituitary gigantism. Accessed July 18, 2025. https://www.icd10data.com/ICD10CM/Codes/E00-E89/E20-E35/E22-/E22.0

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