Appeal Letter

For HCP office staff use only. Do not distribute.

Dear Healthcare Professional,

Please note that the sample patient appeal letter on page 2 of this resource includes general guidance related to appealing treatment decisions and fulfilling prior authorizations. **Please assist your patient in modifying the content in the letter as needed based on your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.** Please be aware that appeal requirements may vary according to health plan. For instance, the plan may require that only the patient submit a letter of appeal. In this case, it is the responsibility of the HCP to provide appropriate supporting documentation under a separate cover.

These enclosures may include Jascayd® (nerandomilast) tablets Prescribing Information, JASCAYD published clinical studies, patient clinical/diagnostic records and related laboratory reports, and high-resolution computed tomography and lung biopsy results indicating idiopathic pulmonary fibrosis (IPF).

Use of the information in this document does not guarantee that the health plan will provide reimbursement for JASCAYD, and it is not intended to be a substitute for, or an influence on, your independent medical judgment.

Before sending the appeal letter to the health plan, please instruct your patient to remove the title that states, "[Sample Appeal Letter: Patient] [Delete this header before sending]."

Reminder for your patients:

How to submit an appeal letter as a patient

How you submit your appeal letter may vary based on your health plan and/or insurer. The health plan insurer or flexible spending account/health savings account provider will specify how appeal letters and additional documentation should be sent (emailed, uploaded through a portal). These details should be included in the letter of denial or may be found in the resources available on their website.

The sample letter on page 2 is one of the resources made available by Boehringer Ingelheim Pharmaceuticals, Inc., to help appeal the insurer's decision to not cover the medication you and your physician have determined to be appropriate for you.

INDICATIONS

JASCAYD is indicated for:

- the treatment of idiopathic pulmonary fibrosis (IPF) in adult patients.
- the treatment of progressive pulmonary fibrosis (PPF) in adult patients.

IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS

- The most common adverse reactions with an incidence of ≥5% in patients treated with JASCAYD were diarrhea, COVID-19, upper respiratory tract infection, depression, weight decreased, decreased appetite, nausea, fatigue, headache, vomiting, back pain, and dizziness.

Please see additional Important Safety Information on page 3 and full Prescribing Information for JASCAYD.

JASCAYD® (nerandomilast) tablets 18 mg | Boehringer Ingelheim

[Sample Appeal Letter: Patient] [Delete this header before sending]

[Date]

[Health Plan Name]

[Health Plan Contact Name]

[Health Plan Mailing Address]

[Patient Name]

[Patient Date of Birth]

[Subscriber ID #]

[Subscriber Group #]

RE: Authorization of Jascayd® (nerandomilast) tablets

Dear Appeal Reviewer,

My name is [Patient name] . I have been diagnosed with idiopathic pulmonary fibrosis (IPF). I am currently under the care of Dr. [Physician name] , who specializes in treating patients with respiratory and lung disorders. [Physician name] has prescribed Jascayd® (nerandomilast) tablets to treat my IPF.

I am writing this letter to appeal your recent decision to deny my doctor's request to use JASCAYD to treat my diagnosed IPF and to ask that you please reconsider this decision and approve the request for treatment. My doctor and I discussed my potential treatment options, and given my medical history and treatment goals, we decided that JASCAYD is the most appropriate treatment option for me.

After discussing your denial from [Denial date] , for [insufficient documentation or medical necessity concerns or other] , my doctor and I believe this issue can be resolved with additional information (included with this letter) and/or a phone call. Being on treatment with JASCAYD is very important to me.

In conclusion, I, [Patient name] , have IPF. My doctor and I discussed my treatment options and agreed that JASCAYD was the most appropriate treatment for me and my circumstances. I ask that you reconsider the decision to deny coverage of this treatment for me.

If you are seeking medical confirmation of my diagnosis or additional information about my medical history, please contact my physician, [Physician name] , who can be reached by phone at [Physician phone number] or email at [Physician email address] .

Thank you for your time and reconsideration of my request for JASCAYD treatment.

Sincerely,

[Patient signature]

Reminder for your patients:

Information to gather before you begin

- ☐ Insurance information (policy number, member ID, group number)
- ☐ Provider information (name, specialty, practice name, practice address, practice phone number)
- ☐ Letter of denial information (date of letter, letter's signee, reason given for decision)
- ☐ Additional medical history (work with your physician to determine what information to include)
- ☐ Clinical support and documentation (work with your physician to supply copies of all lab results and reports)

Your physician and the staff at their practice will be invaluable resources throughout the appeal process. They have worked with many patients to obtain medications that were initially denied.

IMPORTANT SAFETY INFORMATION (CONT'D)

DRUG INTERACTIONS

Effects of Other Drugs on JASCAYD

- **Strong CYP3A Inhibitors:** Reduce the dosage of JASCAYD to 9 mg twice daily when used concomitantly with strong CYP3A inhibitors. Nerandomilast is a CYP3A substrate. Concomitant use of JASCAYD with a strong CYP3A inhibitor increases exposure of nerandomilast, which may increase the risk of JASCAYD adverse reactions.

- **Moderate or Strong CYP3A Inducers:** Avoid use of JASCAYD with strong or moderate CYP3A inducers. Nerandomilast is a CYP3A substrate. Concomitant use of JASCAYD with moderate or strong CYP3A inducers is expected to decrease exposure of nerandomilast, which may decrease the efficacy of JASCAYD.

- **Pirfenidone:** Recommended dosage of JASCAYD is 18 mg twice daily when used concomitantly with pirfenidone. Do not reduce the dosage to 9 mg twice daily. Concomitant use of JASCAYD with pirfenidone decreases exposure of nerandomilast in patients with IPF. When JASCAYD was used concomitantly with pirfenidone in patients with IPF in FIBRONEER-IPF, efficacy was not observed with the JASCAYD 9 mg twice daily dosage.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** Advise pregnant women and females of reproductive potential of the potential risk of fetal loss.

- **Renal Impairment:** Use of JASCAYD is not recommended in patients with end stage renal disease (eGFR <15 mL/minute/1.73 m^2).

- **Hepatic Impairment:** Use of JASCAYD is not recommended in patients with severe (Child-Pugh Class C) hepatic impairment.

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Please see full Prescribing Information for JASCAYD.