Medical Necessity Letter
For HCP office staff use only. Do not distribute.

Dear Healthcare Professional,

Please note that the sample patient letter of medical necessity 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 prior authorization requirements may vary according to health plan. For instance, the plan may require that only the patient submit a letter of medical necessity. 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 progressive pulmonary fibrosis (PPF).

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 letter of medical necessity to the health plan, please instruct your patient to remove the title that states, "[Sample Letter of Medical Necessity: Patient] [Delete this header before sending]."

Reminder for your patients:

How to submit a letter of medical necessity as a patient

How you submit your letter of medical necessity 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 letters and documentation should be sent (emailed, uploaded through a portal). Many insurers have resources available on their website to help facilitate this process, including their own forms and points of contact.

The sample letter on page 2 is one of the resources made available by Boehringer Ingelheim Pharmaceuticals, Inc., to help expedite the approval process and get you on the treatment 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 Letter of Medical Necessity: 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 Sir or Madam,

I am writing as a patient to show medical necessity and obtain authorization for Jascayd® (nerandomilast) tablets on behalf of myself, [Patient Name] , because I have been diagnosed with progressive pulmonary fibrosis (PPF).

Based on conversations I have had with my doctor, [Physician name] , we believe that JASCAYD is an appropriate treatment for me. JASCAYD will be used by me to treat my PPF. I have been informed of the risks and benefits of JASCAYD by my doctor.

My disease state, prior treatments, and response to those treatments, as well as other underlying health issues, age, and other factors that impact my condition are:

[Rationale for treatment]

In conclusion, I, [Patient Name] , have PPF and am requesting approval for JASCAYD treatment.

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 prompt attention and consideration.

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)
- ☐ Your 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 prior authorization process. They have worked with many patients to obtain authorization for medications.

Please see Important Safety Information on previous and next page and full Prescribing Information for JASCAYD.

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.