MIRATI&Me®

Letters for coverage requests

Samples and support

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INDICATION

KRAZATI® (adagrasib) is indicated for the treatment of adult patients with *KRAS G12C*-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA-approved test, who have received at least one prior systemic therapy.

This indication is approved under accelerated approval based on objective response rate (ORR) and duration of response (DOR). Continued approval for this indication may be contingent upon verification and description of a clinical benefit in a confirmatory trial(s).

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Gastrointestinal Adverse Reactions

- KRAZATI can cause severe gastrointestinal adverse reactions

Please see Indication and Important Safety Information on page 6.

Please click here for Full Prescribing Information.

KRAZATI® (adagrasib) | 200 mg TABLETS

Submitting a letter of appeal

You may need to provide a letter of appeal if:

- Your patient's claim was denied by their health insurance provider
- You want the health insurance provider to reconsider the decision

Submitting a letter of medical necessity

You may need to provide a letter of medical necessity (LMN) if:

- Your patient's claim was denied, and you have submitted an appeal letter
- You are requesting a formulary exception or tiering exception to get access for your patient

Information you will need

When writing either type of letter, make sure you have the following for the most efficient request:

- Patient's full name and date of birth
- Patient's insurance policy/ID number
- Claim number if a decision on an appeal has already been made
- A brief clinical history, including diagnosis, current symptoms, treatment dates, and International Classification of Disease (ICD) code(s)
- Supporting evidence for your recommendation (see page 5 for suggestions)
- Your office contact information
- The reason given for the coverage denial (LMN only)

If you or your patient has questions, **call Mirati & Me at 844-647-2842,** Monday through Friday, 8 AM to 8 PM ET, or scan to visit **MiratiandMe.com**

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Sample letter of appeal

Ask the payer whether a specific form is required to help request an appeal.

Follow up with the payer if your office does not receive notification of the decision in a timely manner.

Sample Letter of Appeal

Claim number: [Claim number]
Submission date: [Date]
Denial date: [Date]

[Physician's letterhead]

[Date]

[Prior authorization department or contact name]
[Name of health insurance company]
[Insurance company's address]
[City, state, ZIP code]

Patient: [Patient's name]
Patient ID: [Patient's plan-specific member ID]
Date of birth: [Patient's date of birth]
Policyholder: [Policyholder's name]
Group number: [Policyholder's group number]
Diagnosis: [ICD-10-CM code or diagnosis]

ATTN: Prior Authorization/Appeals Department

To whom it may concern,

My name is [Physician's name], and I am writing on behalf of my patient, [Patient's name], to request a review of your denial of coverage for [Product name]. [Patient's name] has been under my care for the treatment of [Patient's condition].

I understand that the reason for your denial is [copy reason verbatim from the plan's denial letter]. However, in my opinion, [Product name] is the appropriate treatment for my patient.

In support of that judgment, I will share the patient's relevant clinical history. [Provide a brief medical history, including diagnosis, allergies, existing comorbidities, and International Classification of Diseases (ICD) code(s)].

[Discuss rationale for using product vs other treatments. Insert your recommendation summary here, including your professional opinion of your patient's prognosis or disease progression without this treatment]. See below for the list of enclosed documents that support this view. Based on this information, I ask that you provide coverage of [Product name] for my patient.

Please feel free to contact either me at [Physician's phone number] or [Patient's name] at [Patient's phone number] for any additional information you may require. My patient and I look forward to receiving your timely response and approval of this claim.

Thank you for your time and consideration.

Sincerely,

[Physician's signature]

[Physician name] [Physician NPI] [Name of practice]
[Physician's phone number]
[Physician's fax number]
[Physician's email address]

This information is provided as an example and is meant for educational purposes only. Mirati Therapeutics cannot guarantee insurance coverage or reimbursement. Coverage and reimbursement may vary significantly by payer, plan, patient, and setting of care. It is the sole responsibility of the health care provider to include the proper information and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

Digital version available at MiratiandMe.com.

Sample letter of medical necessity

Ask the payer whether a specific form is required to help establish medical necessity.

Follow up with the payer if your office does not receive notification of the decision in a timely manner.

Sample Letter of Medical Necessity

[Physician's letterhead]

[Date]

[Name of pharmacy director or payer contact]
[Contact's title]
[Name of health plan company]
[Health plan address]
[City, state, ZIP code]

Patient: [Patient's name]
Date of birth: [Patient's date of birth]
Patient ID: [Patient's plan-specific member ID]
Policyholder: [Policyholder's name]
Group number: [Policyholder's group number]

Re: Coverage for [Product name]

Dear [Pharmacy director or payer contact name],

I am writing on behalf of my patient, [Patient's name], to request coverage for [Product name]. I have enclosed the relevant patient information to document the medical necessity to support my request.

Patient Summary

[Patient's name] is [age] years old and was initially diagnosed with [Diagnosis] [ICD-10-CM code] on [Date]. [Patient name] has been under my care since [Date].

[Provide details of the patient's clinical history, current symptoms and condition, any potential contraindications, and any relevant laboratory test results, highlighting the factors that have led you to recommend use of the product.]

Rationale for Treatment

[Include relevant medical information to support the product as the appropriate treatment option. Insert your professional opinion of the patient's prognosis if they do not receive this treatment.]

In my medical judgment, [Product name] is medically necessary to treat my patient's condition, and I ask you to please consider coverage of [Product name] on [Patient's name]'s behalf. Please refer to the enclosed supporting documents for further details, and do not hesitate to contact me at [Physician's phone number] or via email at [Physician's email]. Thank you for your time and consideration.

Sincerely,

[Physician's signature]

[Physician name] [Physician NPI] [Name of practice]

Enclosures: [List and attach additional documents, which may include Prescribing Information, clinical notes/medical records, US Food and Drug Administration approval letter, clinical studies and efficacy data, and/or clinical practice guidelines.]

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Information to support your medical judgment

Valued recommendations

To strengthen your requests for coverage, you may wish to include the following recommendations provided by the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)

CATEGORY 2A
NCCN
RECOMMENDED

NON-SMALL CELL LUNG CANCER (NSCLC)

NCCN Guidelines® recommend adagrasib (KRAZATI®) as a subsequent therapy option for patients with ***KRAS G12C*-mutated advanced or metastatic NSCLC after progression (Category 2A)**.[1]

CENTRAL NERVOUS SYSTEM (CNS) CANCERS

NCCN Guidelines for CNS cancers recommend adagrasib (KRAZATI) as a systemic therapy option for patients with ***KRAS G12C*-mutated advanced NSCLC with brain metastases (Category 2A)**.[2]

PANCREATIC ADENOCARCINOMA

NCCN Guidelines for pancreatic adenocarcinoma recommend adagrasib (KRAZATI) as a subsequent systemic therapy option for patients with ***KRAS G12C*-mutated advanced NSCLC with pancreatic adenocarcinoma (Category 2A** recommendation for ECOG PS 0-2 and NCCN category 2B for ECOG PS 3-4).[3]

COLON CANCER

NCCN Guidelines recommend adagrasib (KRAZATI) plus cetuximab or panitumumab as a subsequent therapy option for ***KRAS G12C*-mutated advanced or metastatic colon cancer (Category 2A).** For patients unable to tolerate an EGFR inhibitor due to toxicity, single-agent adagrasib can be considered (Category 2A).[4]

RECTAL CANCER

NCCN Guidelines recommend adagrasib (KRAZATI) plus cetuximab or panitumumab as a subsequent therapy option for ***KRAS G12C*-mutated advanced or metastatic rectal cancer (Category 2A).** For patients unable to tolerate an EGFR inhibitor due to toxicity, single-agent adagrasib can be considered (Category 2A).[5]

Investigational Use: These clinical practice guidelines may contain information about investigational uses of adagrasib (a Mirati product). The efficacy and safety of adagrasib for the investigational uses described have not been approved by the US Food and Drug Administration. There is no guarantee adagrasib will become commercially available for the uses under investigation.

Mirati resources

The resources below may be of further help. Please feel free to view them at your convenience.

- Existing Mirati presentations and publications
- The collection of forms and resources on the Mirati & Me website
- NCCN.org
- Full Prescribing Information for KRAZATI

CNS, central nervous system; ECOG PS, Eastern Cooperative Oncology Group performance status; FDA, US Food and Drug Administration.

References: 1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Non-Small Cell Lung Cancer V.5.2023. © National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed November 28, 2023. To view the most recent and complete version of the guideline, go online to NCCN.org. **2.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Central Nervous System Cancers V.1.2023. © National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed November 28, 2023. To view the most recent and complete version of the guideline, go online to NCCN.org. **3.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Pancreatic Adenocarcinoma V.2.2023. © National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed November 28, 2023. To view the most recent and complete version of the guideline, go online to NCCN.org. **4.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Colon Cancer V.4.2023. © National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed November 28, 2023. To view the most recent and complete version of the guideline, go online to NCCN.org. **5.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Rectal Cancer V.6.2023. © National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed November 28, 2023. To view the most recent and complete version of the guideline, go online to NCCN.org.

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INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

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IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Gastrointestinal Adverse Reactions

- KRAZATI can cause severe gastrointestinal adverse reactions
- Monitor and manage patients using supportive care, including antidiarrheals, antiemetics, or fluid replacement, as indicated. Withhold, reduce the dose, or permanently discontinue KRAZATI based on severity

QTc Interval Prolongation

- KRAZATI can cause QTc interval prolongation, which can increase the risk for ventricular tachyarrhythmias (eg, torsades de pointes) or sudden death
- Avoid concomitant use of KRAZATI with other products with a known potential to prolong the QTc interval. Avoid use of KRAZATI in patients with congenital long QT syndrome and in patients with concurrent QTc prolongation
- Monitor ECGs and electrolytes prior to starting KRAZATI, during concomitant use, and as clinically indicated in patients with congestive heart failure, bradyarrhythmias, electrolyte abnormalities, and in patients who are taking medications that are known to prolong the QT interval. Withhold, reduce the dose, or permanently discontinue KRAZATI, depending on severity

WARNINGS AND PRECAUTIONS (continued)

Hepatotoxicity

- KRAZATI can cause hepatotoxicity, which may lead to drug-induced liver injury and hepatitis
- Monitor liver laboratory tests (AST, ALT, alkaline phosphatase, and total bilirubin) prior to the start of KRAZATI, and monthly for 3 months or as clinically indicated, with more frequent testing in patients who develop transaminase elevations. Reduce the dose, withhold, or permanently discontinue KRAZATI based on severity

Interstitial Lung Disease/Pneumonitis

- KRAZATI can cause interstitial lung disease (ILD)/pneumonitis, which can be fatal
- Monitor patients for new or worsening respiratory symptoms indicative of ILD/pneumonitis (eg, dyspnea, cough, fever) during treatment with KRAZATI
- Withhold KRAZATI in patients with suspected ILD/pneumonitis and permanently discontinue KRAZATI if no other potential causes of ILD/pneumonitis are identified

Adverse Reactions

- The most common adverse reactions in NSCLC patients (≥20%) are diarrhea, nausea, fatigue, vomiting, musculoskeletal pain, hepatotoxicity, renal impairment, dyspnea, edema, decreased appetite, cough, pneumonia, dizziness, constipation, abdominal pain, and QTc interval prolongation

Females and Males of Reproductive Potential

- Infertility: Based on findings from animal studies, KRAZATI may impair fertility in females and males of reproductive potential

MIRATI THERAPEUTICS

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