LUMAKRAS™
(sotorasib) 120 mg tablets

Access Guide

- Product overview & dosing guidelines
- Coverage & co-pay details
- Provider & patient resources

INDICATION

LUMAKRAS™ 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 overall response rate (ORR) and duration of response (DOR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

IMPORTANT SAFETY INFORMATION

Hepatotoxicity

- LUMAKRAS™ can cause hepatotoxicity, which may lead to drug-induced liver injury and hepatitis.
- Among 357 patients who received LUMAKRAS™ in CodeBreaK 100, hepatotoxicity occurred in 1.7% (all grades) and 1.4% (grade 3). A total of 18% of patients who received LUMAKRAS™ had increased alanine aminotransferase (ALT)/increased aspartate aminotransferase (AST); 6% were grade 3 and 0.6% were grade 4. In addition to dose interruption or reduction, 5% of patients received corticosteroids for the treatment of hepatotoxicity.
- Monitor liver function tests (ALT, AST, and total bilirubin) prior to the start of LUMAKRAS™, every 3 weeks for the first 3 months of treatment, then once a month or as clinically indicated, with more frequent testing in patients who develop transaminase and/or bilirubin elevations.
- Withhold, dose reduce, or permanently discontinue LUMAKRAS™ based on severity of adverse reaction.

Please see page 8 for LUMAKRAS™ Important Safety Information. Please see LUMAKRAS™ full Prescribing Information.

A first-in-class treatment option for patients with NSCLC and the *KRAS G12C* mutation[1]

LUMAKRAS™ (sotorasib) 120 mg tablets

What it is

- Treatment option for adult patients with *KRAS G12C*-mutated locally advanced or metastatic 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 overall response rate (ORR) and duration of response (DOR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).[1]
- Oral therapy to be taken daily, until disease progression or unacceptable toxicity.[1]

What it does

- Forms an irreversible, covalent bond with the unique cysteine of $KRAS^{G12C}$, locking the protein in an inactive state that prevents downstream signaling without affecting wild-type KRAS.[1]

How to determine if patients have *KRAS G12C*

- *KRAS G12C* can be detected in tissue and liquid biopsy specimens using well-validated common molecular testing methods.[2,3]
  - Most NGS panels already include *KRAS G12C.*[3]
  - Consider adding *KRAS G12C* when ordering single-gene biomarker tests.[4,5]

LUMAKRAS™ supplied in 1 bottle of 240 tablets.[1]
Bottle and packaging are not to scale.

For information on diagnostic testing coverage and reimbursement, see Diagnostic Testing Access Guide

References: 1. LUMAKRAS™ (sotorasib) prescribing information, Amgen. **2.** Leighl NB, et al. *Clin Cancer Res*. 2019;25:4691-4700. **3.** Sherwood JL, et al. *ESMO Open*. 2017;2:e00235. doi:10.1136/esmoopen-2017-000235. **4.** Lindeman NI, Cagle PT, Aisner DL, et al. *Arch Pathol Lab Med*. 2018;142(3):321-346. **5.** Kalemkerian GP, et al. *J Clin Oncol*. 2018;36:911-919.

IMPORTANT SAFETY INFORMATION

Interstitial Lung Disease (ILD)/Pneumonitis

- LUMAKRAS™ can cause ILD/pneumonitis that can be fatal. Among 357 patients who received LUMAKRAS™ in CodeBreaK 100 ILD/pneumonitis occurred in 0.8% of patients, all cases were grade 3 or 4 at onset, and 1 case was fatal. LUMAKRAS™ was discontinued due to ILD/pneumonitis in 0.6% of patients.
- Monitor patients for new or worsening pulmonary symptoms indicative of ILD/pneumonitis (eg, dyspnea, cough, fever). Immediately withhold LUMAKRAS™ in patients with suspected ILD/pneumonitis and permanently discontinue LUMAKRAS™ if no other potential causes of ILD/pneumonitis are identified.

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Dosing

LUMAKRAS™ (sotorasib) 120 mg tablets

Recommended dosage

- The recommended dosage of LUMAKRAS™ is 960 mg (eight 120 mg tablets) orally once daily until disease progression or unacceptable toxicity.[1]
- Patients should take LUMAKRAS™ at the same time each day with or without food.[1]
- LUMAKRAS™ tablets should be swallowed whole. Patient should not chew, crush, or split tablets. For patients who have difficulty swallowing solids, LUMAKRAS™ can be dispersed in 120 mL (4 ounces) of non-carbonated water without crushing. See full Prescribing Information for more information.[1]
- If vomiting occurs after taking LUMAKRAS™, patient should not take an additional dose. The next dose should be taken the next day as prescribed.[1]

Missed dose

- If a patient misses a dose of LUMAKRAS™ by more than 6 hours, the next dose should be taken the next day as prescribed. Do not take 2 doses at the same time to make up for the missed dose.[1]

Recommended dose reductions

- If adverse reactions occur, a maximum of 2 dose reductions are permitted.[1]

First Dose Reduction (480 mg)

4× 120 mg tablets once daily

Second Dose Reduction (240 mg)

2× 120 mg tablets once daily

LUMAKRAS™ should be discontinued if patients are unable to tolerate the minimum dose of 240 mg once daily.[1]

Tablets are not to scale.

Reference: 1. LUMAKRAS™ (sotorasib) prescribing information, Amgen.

Coverage for LUMAKRAS™

LUMAKRAS™ (sotorasib) 120 mg tablets

Coverage and out-of-pocket cost will vary by patient. Check with your patient's insurance for specific coverage requirements.

If you need additional assistance, Amgen Assist 360™ can help.

Amgen Assist 360™
has tools that can help inform coverage decisions:

For Benefit Verification

- Benefit Verification Request Form

For Prior Authorization & Claim Support

- Guide to LUMAKRAS™ PA Process
- Sample Letter of Medical Necessity
- Sample Letter of Appeal

If you need additional assistance, please contact Amgen Assist 360™:
1-888-4ASSIST (1-888-427-7478), Monday to Friday, 9:00 am to 8:00 pm ET

The Amgen FIRST STEP™ Program is here to help eligible commercially insured patients who have been prescribed LUMAKRAS™

LUMAKRAS™ (sotorasib) 120 mg tablets

$0 for the first month's prescription fill and $5 OOP cost for each subsequent fill

- For eligible commercially insured patients
- No income eligibility requirement

Contact the Amgen FIRST STEP™ Program at 1-888-65-STEP1 or **AMGENFIRSTSTEP.COM** to register or for more information.

TO QUALIFY FOR THE AMGEN FIRST STEP™ PROGRAM, PATIENT:

- Must be prescribed LUMAKRAS™.
- Must have private commercial health insurance that covers medication costs for LUMAKRAS™.
- Must not be a participant in any federal-, state-, or government-funded healthcare program such as Medicare, Medicare Advantage, Medicare Part D, Medicaid, Medigap, Veterans Affairs (VA), the Department of Defense (DoD), or TRICARE®.
- May not seek reimbursement for value received from the Amgen FIRST STEP™ Program from any third-party payers, including flexible spending accounts or healthcare savings accounts. If at any time patients begin receiving coverage under any federal-, state-, or government-funded healthcare program, patients will no longer be eligible to participate in the Amgen FIRST STEP™ Program and must call 1-888-65-STEP1 (1-888-657-8371) Monday through Friday, 9 am-8 pm EST to stop participation. Restrictions may apply. This is not health insurance. Program invalid where otherwise prohibited by law.
- Other restrictions apply. If you become aware that your health plan or pharmacy benefit manager does not allow the use of manufacturer co-pay support as part of your health plan design, you agree to comply with your obligations, if any, to disclose your use of the card to your insurer. Amgen reserves the right to revise or terminate this program, in whole or in part, without notice at any time.

COVERAGE LIMITS/PROGRAM MAXIMUMS:

- Program covers out-of-pocket medication costs for the Amgen product only.
- Ongoing activation of the Amgen FIRST STEP™ card is contingent on the submission of the required Explanation of Benefits (EOB) form by the healthcare provider's office within 45 days of use of the Amgen FIRST STEP™ card. Patients will be responsible for reimbursing the program for all amounts paid out if the EOB for the date of service is not received within 45 days.

Please see page 8 for LUMAKRAS™ Important Safety Information. Please see LUMAKRAS™ full Prescribing Information.

Support from every angle

Rely on Amgen Assist 360™, a single point of contact, to provide support designed around you, your patients, and their caregivers.

FOR YOUR OFFICE

BENEFIT VERIFICATION

Submit, store, and retrieve benefit verifications electronically for all patients currently on Amgen Oncology medications with ease from our secure Amgen Assist 360™ Provider Portal.*

REIMBURSEMENT COUNSELORS

Call an Amgen Reimbursement Counselor directly for your benefit verification needs.

FIELD REIMBURSEMENT SPECIALISTS

Schedule a remote or live appointment with a Field Reimbursement Specialist who can assist with:

- Prior authorization and claims denials/appeals
- Payer-specific inquiries and policy updates
- Financial assistance, including Amgen FIRST STEP™ co-pay program support

AMGEN THERAPY LOCATOR

AmgenTherapyLocator.com is a searchable database that can help locate specialty pharmacies where LUMAKRAS™ can be dispensed.†

CALL 1-888-4ASSIST (1-888-427-7478)
Monday to Friday, 9:00 am to 8:00 pm ET or visit AmgenAssist360.com

*Amgen Assist 360™ can refer patients to independent nonprofit patient assistance programs that may be able to help them afford the co-pay costs for their prescribed medicine.

†The information on this website is reported by independent third-party treatment sites. It is not comprehensive of all sites that handle the therapies listed, and Amgen does not confirm accuracy or otherwise endorse any treatment sites.

Find the resources that matter most for your patients and caregivers

AMGEN ASSIST 360™
Support, Simplified

Rely on Amgen Assist 360™, assistance designed to support patients and their caregivers throughout the treatment journey.

FOR YOUR PATIENTS

SUPPORT FROM AMGEN NURSE NAVIGATORS:

Patients are connected with a single point of contact who can help them find resources that are most important to them.* Amgen Nurse Navigators are there to support, not replace, your treatment plan and are trained to assist a patient with financial coverage and referrals to resources that may help their emotional wellness throughout their treatment journey.†

REFERRALS TO DAY-TO-DAY LIVING RESOURCES:

Patients can learn about independent nonprofit organizations that may provide community resources, one-on-one counseling services, and local support groups.

FINANCIAL AND CO-PAY ASSISTANCE

- For eligible‡ commercially insured patients, the Amgen FIRST STEP™ co-pay program can help.
- For patients with government insurance like Medicare, we provide referrals to independent nonprofit patient assistance programs that may be able to help them afford the co-pay cost of their medicine.*
- For uninsured patients, the Amgen Safety Net Foundation™, a nonprofit patient assistance program sponsored by Amgen, helps qualified patients access Amgen medicines at no cost.

CALL 1-888-4ASSIST (1-888-427-7478)
Monday to Friday, 9:00 am to 8:00 pm ET or visit AmgenAssist360.com

*Resources include referrals to independent nonprofit patient assistance programs. Eligibility for resources provided by independent nonprofit patient assistance programs is based on the nonprofits' criteria. Amgen has no control over these programs and provides referrals as a courtesy only.

†Amgen Nurse Navigators are only available to patients that are prescribed certain products. Nurse Navigators are there to support, not replace, your treatment plan and do not provide medical advice or case management services. Patients should always consult their healthcare provider regarding medical decisions or treatment concerns.

‡Terms, conditions, and program maximums apply. This program is not open to patients receiving prescription reimbursement under any federal-, state-, or government-funded healthcare program. Not valid where prohibited by law.

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Most Common Adverse Reactions

- The most common adverse reactions ≥ 20% were diarrhea, musculoskeletal pain, nausea, fatigue, hepatotoxicity, and cough.

Drug Interactions

- Advise patients to inform their healthcare provider of all concomitant medications, including prescription medicines, over-the-counter drugs, vitamins, dietary and herbal products.
- Inform patients to avoid proton pump inhibitors and H_2 receptor antagonists while taking LUMAKRAS™.
- If coadministration with an acid-reducing agent cannot be avoided, inform patients to take LUMAKRAS™ 4 hours before or 10 hours after a locally acting antacid.

Please see LUMAKRAS™ full Prescribing Information.

A first-in-class treatment option[1]

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Support from every angle

Amgen Assist 360™ provides LUMAKRAS™ support for your office, patients, and caregivers:

For your office

- Benefit verification
- Prior authorization and claims approval support

For patients and caregivers

- Ongoing support through the Amgen Nurse Navigator Program*
- Referrals to day-to-day living resources† and financial assistance

Low out-of-pocket costs for eligible commercially insured patients

- Eligible commercially insured patients may pay as little as $5 with the Amgen FIRST STEP™ program‡

*Amgen Nurse Navigators are only available to patients that are prescribed certain products. Nurse Navigators are there to support, not replace, your treatment plan and do not provide medical advice or case management services. Patients should always consult their healthcare provider regarding medical decisions or treatment concerns.

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