LUMAKRAS®
(sotorasib) 240 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 and increased ALT or AST which may lead to drug-induced liver injury and hepatitis.
- In the pooled safety population of NSCLC patients who received single agent LUMAKRAS 960 mg hepatotoxicity occurred in 27% of patients, of which 16% were Grade ≥ 3. Among patients with hepatotoxicity who required dosage modifications, 64% required treatment with corticosteroids.
- In this pooled safety population of NSCLC patients who received single agent LUMAKRAS 960 mg, 17% of patients who received LUMAKRAS had increased alanine aminotransferase (ALT)/increased aspartate aminotransferase (AST); of which 9% were Grade ≥ 3. The median time to first onset of increased ALT/AST was 6.3 weeks (range: 0.4 to 42). Increased ALT/AST leading to dose interruption or reduction occurred in 9% of patients treated with LUMAKRAS. LUMAKRAS was permanently discontinued due to increased ALT/AST in 2.7% of patients. Drug-induced liver injury occurred in 1.6% (all grades) including 1.3% (Grade ≥ 3).
- In this pooled safety population of NSCLC patients who received single agent LUMAKRAS 960 mg, a total of 40% patients with recent (≤ 3 months) immunotherapy prior to starting LUMAKRAS had an event of hepatotoxicity. An event of hepatotoxicity was observed in 18% of patients who started LUMAKRAS more than 3 months after last dose of immunotherapy and in 17% of those who never received immunotherapy. Regardless of time from prior immunotherapy, 94% of hepatotoxicity events improved or resolved with dosage modification of LUMAKRAS, with or without corticosteroid treatment.
- Monitor liver function tests (ALT, AST, alkaline phosphatase 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, reduce the dose or permanently discontinue LUMAKRAS based on severity of the adverse reaction. Consider administering systemic corticosteroids for the management of hepatotoxicity.

Please see pages 8 and 9 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

LUMAKRAS®
(sotorasib) 240 mg tablets

What it is

- Treatment option for 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).[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 Next Generation Sequencing (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 120 240-mg 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. **4.** Lindeman NI, et al. *Arch Pathol Lab Med*. 2018;142:321-346. **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.
- In the pooled safety population of NSCLC patients who received single agent LUMAKRAS 960 mg ILD/pneumonitis occurred in 2.2% of patients, of which 1.1% were Grade ≥ 3, and 1 case was fatal. The median time to first onset for ILD/pneumonitis was 8.6 weeks (range: 2.1 to 36.7 weeks). LUMAKRAS was permanently discontinued due to ILD/pneumonitis in 1.3% of LUMAKRAS-treated patients. Monitor patients for new or worsening pulmonary symptoms indicative of ILD/pneumonitis (e.g., 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.

Please see pages 8 and 9 for LUMAKRAS Important Safety Information. Please see LUMAKRAS full Prescribing Information.

LUMAKRAS® (sotorasib) is the only once-daily oral *KRAS* G12C therapy[1,2]

LUMAKRAS® (sotorasib) 240 mg tablets

LUMAKRAS® confirmed starting dose: 960 mg orally[1,2]

- Treat until disease progression or unacceptable toxicity[1]

- **Patients should take the daily dose of LUMAKRAS® at the same time each day, with or without food[1]**
- LUMAKRAS® tablets are comparable in size to a dime[1,3]

LUMAKRAS® can be dispersed in water[1]

Administration to patients who have difficulty swallowing solids[1]

- Disperse tablets in 120 mL (4 ounces) of non-carbonated, room-temperature water without crushing. No other liquids should be used
- Stir or swirl the cup for approximately 3 minutes until tablets are dispersed into small pieces (the tablets will not completely dissolve) and drink immediately or within 2 hours. The appearance of the mixture may range from pale yellow to bright yellow
- Swallow the dispersed tablet. Do not chew pieces of the tablet
- Rinse the container with an additional 120 mL (4 ounces) of water and drink. If the mixture is not consumed immediately, stir the mixture again to ensure that tablets are dispersed

Missed Dose or Vomiting[1]

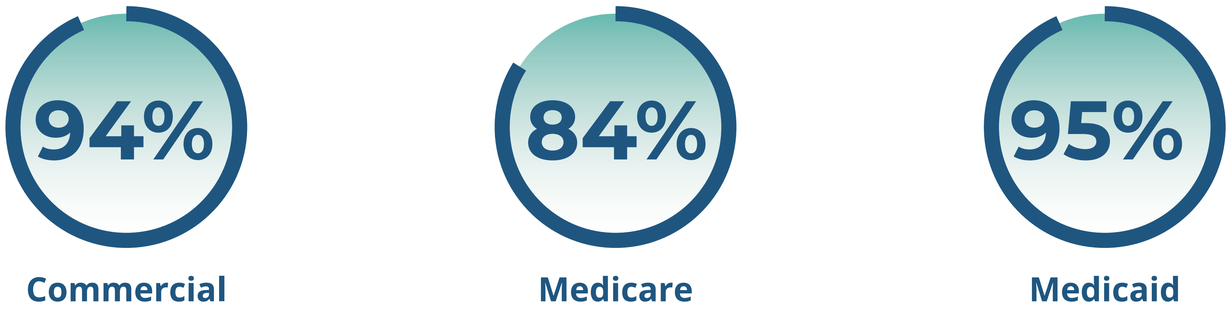
- If a dose of LUMAKRAS® is missed by more than 6 hours, take the next dose as prescribed the next day. Do not take 2 doses at the same time to make up for the missed dose
- If vomiting occurs after taking LUMAKRAS®, do not take an additional dose. Take the next dose as prescribed the next day

KRAS, Kirsten rat sarcoma viral oncogene homolog.

References: 1. LUMAKRAS® (sotorasib) prescribing information, Amgen. **2.** Hochmair MJ, et al. *Eur J Cancer.* 2024;208:114204. **3.** Data on file, Amgen; [Sotorasib Tablet Size]; 2025.

LUMAKRAS® has established broad coverage with 93% of patients covered nationally*,†

LUMAKRAS® (sotorasib) 240 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 SupportPlus can help.

Amgen® SupportPlus
has tools that can help inform coverage decisions:

For Benefits Verification

- Benefits 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 SupportPlus at (866) 264-2778 Monday - Friday, 9:00 am - 8:00 pm ET.

PA, prior authorization.
*Includes 94% commercial, 84% Medicare, 95% Managed Medicaid, and 96% State Medicaid coverage.
†As of October 16, 2024.

Reference: Data on file, Amgen; [Lumakras Payer Coverage-22 Oct 2024].

AMGEN Support+

Amgen® SupportPlus Co-Pay Program

The Amgen SupportPlus Co-Pay Program may help eligible patients with private or commercial insurance lower their out-of-pocket costs.

- Pay as little as **$0* out-of-pocket** for each dose
- Can be applied to deductible, co-insurance, and co-payment*
- No income eligibility requirement

Encourage your patients with private or commercial insurance to check eligibility and enroll at **AmgenSupportPlus.com/copay** or call Amgen SupportPlus at (866) 264-2778.

Call Amgen SupportPlus at (866) 264-2778, Monday - Friday, 9:00 am - 8:00 pm ET or visit **AmgenSupportPlus.com**.

*Eligibility criteria and program maximums apply. See AmgenSupportPlus.com/copay for full **Terms and Conditions.**

AMGEN® Support+

We're right here, right when you need us

Personalized support that you and your patients can count on across Amgen therapies.

HCP Support Center

Our Amgen® SupportPlus Representatives can assist with issues around patient coverage, prior authorizations, co-pay programs, and more.

- Verify patient's insurance plan coverage details
- Identify if there is a payer-mandated pharmacy for prescription fulfillment
- **Amgen SupportPlus Customer Portal:** Submit, store, and retrieve benefits verifications electronically

Field Reimbursement Specialists

A Field Reimbursement Specialist can provide live or virtual coverage and access resources to support your patients.

Amgen Therapy Locator™

Visit **AmgenTherapyLocator.com** to see which specialty pharmacies and distributors supply LUMAKRAS®.*

*The information on the website is reported by independent third-party sites that administer or deliver treatment to patients. It is not comprehensive of all sites that handle the therapies listed, and Amgen does not confirm accuracy or otherwise endorse any of these sites. Note: Coding and coverage policies change periodically and often without warning. The healthcare provider is solely responsible for determining coverage and reimbursement parameters and appropriate coding for his/her own patients and procedures. This information is not a guarantee of coverage or reimbursement.

AMGEN® Support+

Resources for your patients

Financial Support

- The Amgen SupportPlus Co-Pay Program may help eligible patients with private or commercial insurance lower their out-of-pocket costs*
- Amgen SupportPlus can provide your patients with information about independent nonprofit foundations that may be able to help

Amgen® Nurse Partners†

Dedicated Amgen Nurse Partners can offer supplemental support and provide information about resources to help patients access their prescribed medication.

Call Amgen SupportPlus at (866) 264-2778, Monday - Friday, 9:00 am - 8:00 pm ET or visit **AmgenSupportPlus.com**.

*Eligibility criteria and program maximums apply. See AmgenSupportPlus.com/copay for full **Terms and Conditions.**

†Amgen Nurse Partners are only available to patients that are prescribed certain Amgen products. They are not part of your patient's treatment team and do not provide medical advice, nursing, or case management services. Amgen Nurse Partners will not inject patients with Amgen medications. Patients should always consult their healthcare provider regarding medical decisions or treatment concerns.

Important Safety Information

LUMAKRAS® (sotorasib) 240 mg tablets

Hepatotoxicity

- LUMAKRAS can cause hepatotoxicity and increased ALT or AST which may lead to drug-induced liver injury and hepatitis.
- In the pooled safety population of NSCLC patients who received single agent LUMAKRAS 960 mg hepatotoxicity occurred in 27% of patients, of which 16% were Grade ≥ 3. Among patients with hepatotoxicity who required dosage modifications, 64% required treatment with corticosteroids.
- In this pooled safety population of NSCLC patients who received single agent LUMAKRAS 960 mg, 17% of patients who received LUMAKRAS had increased alanine aminotransferase (ALT)/ increased aspartate aminotransferase (AST); of which 9% were Grade ≥ 3. The median time to first onset of increased ALT/AST was 6.3 weeks (range: 0.4 to 42). Increased ALT/AST leading to dose interruption or reduction occurred in 9% of patients treated with LUMAKRAS. LUMAKRAS was permanently discontinued due to increased ALT/AST in 2.7% of patients. Drug-induced liver injury occurred in 1.6% (all grades) including 1.3% (Grade ≥ 3).
- In this pooled safety population of NSCLC patients who received single agent LUMAKRAS 960 mg, a total of 40% patients with recent (≤ 3 months) immunotherapy prior to starting LUMAKRAS had an event of hepatotoxicity. An event of hepatotoxicity was observed in 18% of patients who started LUMAKRAS more than 3 months after last dose of immunotherapy and in 17% of those who never received immunotherapy. Regardless of time from prior immunotherapy, 94% of hepatotoxicity events improved or resolved with dosage modification of LUMAKRAS, with or without corticosteroid treatment.
- Monitor liver function tests (ALT, AST, alkaline phosphatase 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, reduce the dose or permanently discontinue LUMAKRAS based on severity of the adverse reaction. Consider administering systemic corticosteroids for the management of hepatotoxicity.

Interstitial Lung Disease (ILD)/Pneumonitis

- LUMAKRAS can cause ILD/pneumonitis that can be fatal.
- In the pooled safety population of NSCLC patients who received single agent LUMAKRAS 960 mg ILD/pneumonitis occurred in 2.2% of patients, of which 1.1% were Grade ≥ 3, and 1 case was fatal. The median time to first onset for ILD/pneumonitis was 8.6 weeks (range: 2.1 to 36.7 weeks). LUMAKRAS was permanently discontinued due to ILD/pneumonitis in 1.3% of LUMAKRAS-treated patients. Monitor patients for new or worsening pulmonary symptoms indicative of ILD/pneumonitis (e.g., 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.

Important Safety Information (Cont'd)

LUMAKRAS® (sotorasib) 240 mg tablets

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

LUMAKRAS® (sotorasib) 240 mg tablets

LUMAKRAS is indicated for the treatment of 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).

AMGEN® Support+

We're right here, right when you need us

Personalized support that you and your patients can count on across Amgen therapies.

For healthcare professionals

- HCP Support Center
- Field Reimbursement Specialists

For patients and caregivers

- Financial Support
- Amgen® Nurse Partners*

The Amgen® SupportPlus Co-Pay Program may help eligible patients with private or commercial insurance lower their out-of-pocket costs.

- Pay as little as $0† out-of-pocket for each dose
- Can be applied to deductible, co-insurance, and co-payment†
- No income eligibility requirement

*Amgen Nurse Partners are only available to patients that are prescribed certain Amgen products. They are not part of your patient's treatment team and do not provide medical advice, nursing, or case management services. Amgen Nurse Partners will not inject patients with Amgen medications. Patients should always consult their healthcare provider regarding medical decisions or treatment concerns.

†Eligibility criteria and program maximums apply. See AmgenSupportPlus.com/copay for full **Terms and Conditions.**

Reference: LUMAKRAS (sotorasib) prescribing information, Amgen.

Important Safety Information

Most Common Adverse Reactions

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

Please see pages 8 and 9 for LUMAKRAS® Important Safety Information. Please see LUMAKRAS® full Prescribing Information.

AMGEN
One Amgen Center Drive
Thousand Oaks, CA 91320-1799
www.amgen.com