ONCE-DAILY ORAL

LUMAKRAS®

(sotorasib) 120 mg tablets 320 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]

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## 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 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 240 120-mg tablets; or 1 bottle of 90 320-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(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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# LUMAKRAS® is a once-daily oral therapy[1]

- LUMAKRAS recommended dose: 960 mg orally, once daily
  - Treat until disease progression or unacceptable toxicity
- LUMAKRAS can be taken **with or without food**
- LUMAKRAS should be taken **at the same time each day**

## LUMAKRAS has two dosing options for your patient's needs

LUMAKRAS 320 mg tablets


**x3**

**320 mg tablets once daily**

- LUMAKRAS 320 mg tablets have a "beige" color and are supplied in one bottle containing 90 tablets

LUMAKRAS 120 mg tablets

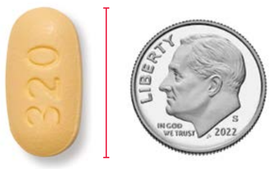

**x8**

**120 mg tablets once daily**

- LUMAKRAS 120 mg tablets have a "yellow" color and are supplied in one bottle containing 240 tablets

## LUMAKRAS tablets compare in size to a dime[2*]

LUMAKRAS 320 mg tablets




LUMAKRAS 120 mg tablets


*Tablets as seen on screen may not reflect actual size; scale to dime.

## 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]

**References: 1.** LUMAKRAS (sotorasib) prescribing information, Amgen. **2.** Data on file, Amgen [Sotorasib Tablet Size, 120 mg & 320 mg]; 2023.

# LUMAKRAS® has established broad coverage with 95% of patients covered nationally[1]*†


**Commercial**


**Medicare**


**Medicaid**

Coverage and out-of-pocket cost will vary by patient. Check with your patient's insurance for
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 93% commercial, 99% Medicare, 97% Managed Medicaid, and 94% State Medicaid coverage.
†As of September 2022.

**Reference: 1.** Data on file, Amgen; [Pharmacy Benefit coverage for Lumakras, Sept 30, 2022].

# 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.

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*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

## Amgen® Access Specialists

An Amgen Access 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.

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† 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.

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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.

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# A first-in-class treatment option[1]

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

**For healthcare professionals**

- HCP Support Center
- Amgen® Access 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.

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