LUMAKRAS®
(sotorasib) tablets
320 mg | 240 mg | 120 mg

A guide to LUMAKRAS® prior authorizations (PAs)*

- **The prescriber has identified the appropriate patient and prescribed LUMAKRAS®**
- **Considerations for collecting the appropriate information and documentation for the PA process**

*Specific plan requirements may vary.

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 full Important Safety Information on Page 4. Click here for full Prescribing Information.

Your LUMAKRAS® patient's insurance may require a PA

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Here are some considerations:

This resource may help you organize specific information about your patient's diagnosis and treatment history to complete a LUMAKRAS® PA.

Please note that PA criteria may vary by health plan, and be sure to confirm the PA criteria and documentation required by your patient's insurer.

Identify the correct diagnosis

- Primary and secondary ICD-10-CM diagnosis codes

Reference patient's previous and current treatment history from their chart

- Electronic medical records should indicate the current treatment, first-line treatments, and other current medications
- *KRAS* G12C diagnostic test or test result with dates (any test showing *KRAS* G12C mutation can be used)

Document prior therapy

- Patients must have received at least one systemic therapy prior to using LUMAKRAS®

Note: Documentation may be required by your patient's insurance. Make sure you read the PA criteria carefully and include all the necessary documents specifically required. Examples may include medical records, clinical chart notes, and claims histories.

TIP: If the patient has a previously approved LUMAKRAS® PA and the same insurance, make sure to start a PA Renewal or Reauthorization.

IMPORTANT SAFETY INFORMATION (Cont'd)

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.

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Identify the correct diagnosis

- **Find the diagnosis the prescriber has documented** in the chart notes and look for it on the PA
- **If you don't see the patient's diagnosis on the PA, don't worry!** Consult with the prescriber before you proceed since selecting the incorrect diagnosis may delay the approval

Diagnostic code example, ICD-10-CM codes:

C34.00 – C34.02	Malignant neoplasm of bronchus and lung; main bronchus	**C34.30 – C34.32**	Malignant neoplasm of bronchus and lung; lower lobe
C34.10 – C34.12	Malignant neoplasm of bronchus and lung; upper lobe	**C34.80 – C34.82**	Malignant neoplasm of bronchus and lung; overlapping sites
C34.2	Malignant neoplasm of bronchus and lung; middle lobe	**C34.90 – C34.92**	Malignant neoplasm of bronchus and lung; unspecified part

Codes identified above are provided as a courtesy only and are not comprehensive or instructive. Coding and coverage policies can change without warning. The healthcare provider is solely responsible for determining coverage, coding, and reimbursement. Amgen does not guarantee coverage or reimbursement. Please check with the payer to verify codes and special billing requirements.

Reference patient's previous and current treatment history from their chart

- Patients will need to have completed previous therapy for locally advanced or metastatic NSCLC
- Patients will need to have a documented *KRAS* mutation

Diagnostic test example, *KRAS* test CPT codes:

Single gene: 81275 and 81276

NGS: 81445, 81456, and 81479

Document prior therapy

- Patient medical/treatment history
- Previous therapies used to treat the patient
- Relevant biomarker test results
- Clinical rationale documenting medical necessity for treatment

Some payers may require additional information or documentation. Along with the information listed, the criteria could include:

- **Documented disease progression** on one prior therapy
- **Medical reason** why a patient cannot start or remain on a different therapy
  - Drug interactions
  - Adverse event risk profile
  - Patients that have specific dosing and/or administration requirements
- **Confirmation** that LUMAKRAS® is being used as monotherapy

ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; CPT= Current Procedural Terminology; NGS=next-generation sequencing.

IMPORTANT SAFETY INFORMATION (Cont'd)

Most Common Adverse Reactions

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

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An Amgen® Access Specialist can provide coverage and access resources to support your patients, such as:

- Help with navigating PA appeals and fulfillment processes
- Educating on payer requirements and necessary documentation for individual patient support

Learn more at AmgenSupportPlus.com

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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.

Click here for LUMAKRAS® full Prescribing Information.

REFERENCE: LUMAKRAS® (sotorasib) prescribing information, Amgen.

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