LUMAKRAS™

(sotorasib) 120 mg tablets

Information on the LUMAKRAS™ prior authorization process

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 back cover for LUMAKRAS™ full Important Safety Information, and see accompanying LUMAKRAS™ full Prescribing Information.

Information on navigating the payer approval process*

Common documentation requirements that may be helpful in the prior authorization (PA) process:

1) **Diagnosis details (chart notes)**
   - Primary and secondary ICD-10-CM diagnosis codes
2) **History of treatment (chart notes)**
   - 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)
3) **Prior therapy**
   - Patients must have received at least one systemic therapy prior to using LUMAKRAS™[1]

*Specific plan requirements may vary.

Diagnosis code example

ICD-10-CM codes[2]:

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

Diagnostic tests example

KRAS test CPT codes[3]:

- Single gene: 81275 and 81276
- NGS: 81445, 81455, and 81479

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.

ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; CPT= Current Procedural Terminology

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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Important information for submitting claims

The information contained herein is for informational purposes only and is provided solely as a courtesy to assist in the submission of claims in an effort to address the needs of patients.

Correct and Complete Patient Information

- Patient name & ID number
- Health insurer name and/or group number
- Provider name & national ID number
- Provider contact information

Collect Relevant Information

- Diagnosis code to the highest level of specificity
- Determine PA criteria (if required)

Supplemental Documentation Considerations (including test results and date as requested)

- Patient medical/treatment history
- Previous therapies the patient has been on
- Relevant biomarker test results
- Clinical rationale documenting medical necessity for treatment

Payer Requirements (if applicable)

- Specialty pharmacy mandate

IMPORTANT SAFETY INFORMATION

Most Common Adverse Reactions

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

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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.

Please see LUMAKRAS™ full Prescribing Information.

REFERENCES

1. LUMAKRAS™ (sotorasib) prescribing information, Amgen.
2. Centers for Disease Control and Prevention/National Center for Health Statistics. ICD-10-CM. Accessed November 18, 2020. https://icd10cmtool.cdc.gov/?fy=FY2021&q=lung%20neoplasm
3. Centers for Medicare & Medicaid Services. Physician Fee Schedule Search. Revised October 30, 2020. Accessed November 18, 2020. https://www.cms.gov/apps/physician-fee-schedule/search/search-criteria.aspx

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