Note: This example letter is provided as a courtesy and not intended to be a directive. Physicians should exercise medical judgment and discretion to appropriately diagnose and characterize the individual patient's medical condition. In addition, HCPs are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement.

LUMAKRAS® (sotorasib) Sample Letter of Medical Necessity

[Physician Letterhead]

[Insurance Company]
[Address Line 1]
[Address Line 2]

RE: Patient Name: _____
Policy ID: _____
Policy Group: _____
Date of Birth: _____

[Date]

Attn [Medical/Pharmacy Director], [Department]:

Dear [Medical/Pharmacy Director]:

I am writing on behalf of [Patient's Name] to formally document the medical necessity for treatment with LUMAKRAS for a diagnosis of [Patient's Diagnosis] .
[If prior authorization has been submitted previously, indicate date of submission and the outcome.]
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). This letter provides additional information and clinical rationale in support of the medical necessity for [Initiating/Continuing/Reinitiating] treatment with LUMAKRAS.

Patient Medical History and Treatment Rationale:

[You may want to consider including the following information, depending on your patient's history of treatment with LUMAKRAS]

[FOR LUMAKRAS INITIATION – patients who have not been treated with LUMAKRAS previously]
- Include the patient's history, diagnosis, and relevant biomarker test results.
- Include any previous therapies the patient has been on.
- Include a summary of your professional opinion and potential prognosis for treatment with LUMAKRAS.
- Include clinical rationale documenting medical necessity for initiation of treatment.

[FOR LUMAKRAS CONTINUATION – patients who are currently treated with LUMAKRAS]
- Include the patient's history, diagnosis, and relevant biomarker test results.
- Include any previous therapies the patient has been on.
- Include a summary of the patient's clinical response to treatment and impact to daily life.
- Include clinical rationale documenting medical necessity for continuation of treatment.

[FOR LUMAKRAS DOSE WITHHOLDING – patients who have interrupted treatment with LUMAKRAS]
- Include the patient's history, diagnosis, and relevant biomarker test results.
- Include dates of LUMAKRAS initiation and dose withholding.
- Include reasons for interrupting therapy.
- Include a summary of the patient's condition and a clinical rationale for dose withholding LUMAKRAS.

In summary, treatment with LUMAKRAS is medically necessary for [Patient's Name] . It is consistent with the current standards of care and is in accordance with the FDA-approved indication.

Please call my office at [Office Phone Number] if I can provide you with additional information to approve my request.

Sincerely,
[Physician's Name]

[List enclosures as appropriate: Examples of enclosures include excerpt(s) from patient's medical record, biomarker test results, relevant treatment guidelines, and product Prescribing Information.]

Please see LUMAKRAS® Indication and LUMAKRAS® Important Safety Information on next page.

This page is for your reference only. Content on this page does not need to be sent to the insurance company.

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.

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.

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.

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

© 2024 Amgen Inc. All rights reserved.
USA-510-81740 10/24