Reference number(s)
4766-A

SPECIALTY GUIDELINE MANAGEMENT

LUMAKRAS (sotorasib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved 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.

B. Compendial Uses
1. Recurrent, advanced, or metastatic KRAS G12C-mutated NSCLC
2. Pancreatic adenocarcinoma
3. Colorectal cancer
4. Ampullary adenocarcinoma

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: Documentation of the presence of KRAS G12C mutation in tumor or plasma specimens.

III. CRITERIA FOR INITIAL APPROVAL

A. Non-Small Cell Lung Cancer (NSCLC)
Authorization of 12 months may be granted for treatment of KRAS G12C-mutated recurrent, advanced or metastatic NSCLC in members who have received at least one prior systemic therapy, as a single agent.

B. Pancreatic Adenocarcinoma
Authorization of 12 months may be granted for treatment of recurrent, locally advanced or metastatic pancreatic adenocarcinoma when all of the following criteria are met:
1. The tumor or plasma specimen is positive for the KRAS G12C mutation.
2. The member has an ECOG (Eastern Cooperative Oncology Group) performance status of 0-2
3. The requested medication will be used as a single agent

C. Colorectal Cancer
Authorization of 12 months may be granted for treatment of advanced or metastatic colorectal cancer, including appendiceal adenocarcinoma and anal adenocarcinoma, when all of the following criteria are met:
1. The tumor or plasma specimen is positive for the KRAS G12C mutation.

2. The requested medication will be used as a single agent, or in combination with cetuximab (Erbitux) or panitumumab (Vectibix).
3. The member previously received treatment with chemotherapy.

D. Ampullary Adenocarcinoma

Authorization of 12 months may be granted for treatment of progressive ampullary adenocarcinoma when all of the following criteria are met:

1. The tumor or plasma specimen is positive for the KRAS G12C mutation.
2. The requested medication will be used as a single agent.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Lumakras [package insert]. Thousand Oaks, CA: Amgen Inc.; April 2023.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed March 5, 2024.
3. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Colon Cancer. Version 1.2024. Accessed March 5, 2024. https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf
4. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Anal Carcinoma. Version 1.2024. Accessed March 5, 2024. https://www.nccn.org/professionals/physician_gls/pdf/anal.pdf