

Specialty Guideline Management

Lumakras

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Lumakras	sotorasib

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.

FDA-approved Indications¹

Lumakras as a single agent 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.

Lumakras, in combination with panitumumab, is indicated for the treatment of adult patients with KRAS G12C-mutated metastatic colorectal cancer (mCRC), as determined by an FDA-approved test, who have received prior fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy.

Compendial Uses²⁻³

- Recurrent, advanced, or metastatic NSCLC
- Pancreatic adenocarcinoma
- Colorectal cancer
- Ampullary adenocarcinoma

- Small bowel adenocarcinoma
- Appendiceal neoplasms and cancers

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

Documentation

Submission of the following information is necessary to initiate the prior authorization review, where applicable:

- KRAS G12C mutation status
- BRAF mutation status

Coverage Criteria

Non-Small Cell Lung Cancer (NSCLC)^{1,2}

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.

Pancreatic Adenocarcinoma²

Authorization of 12 months may be granted for subsequent treatment of KRAS G12C-mutated recurrent, locally advanced, or metastatic pancreatic adenocarcinoma, as a single agent when the member has an ECOG (Eastern Cooperative Oncology Group) performance status of 0-2.

Colorectal Cancer¹⁻³

Authorization of 12 months may be granted for treatment of KRAS G12C-mutated colorectal cancer, including anal adenocarcinoma, when any of the following criteria are met:

- The requested medication will be used as a single agent for BRAF wild-type unresectable, inoperable, or metastatic disease
- The requested medication will be used in combination with cetuximab [Erbix] or panitumumab [Vectibix] for BRAF wild-type advanced or metastatic disease, as subsequent therapy
- The requested medication will be used as a single agent or in combination with cetuximab [Erbix] or panitumumab [Vectibix] for unresectable metachronous metastases, as initial therapy

Ampullary Adenocarcinoma²

Authorization of 12 months may be granted for treatment of KRAS G12C-mutated progressive ampullary adenocarcinoma, as a single agent.

Small Bowel Adenocarcinoma²

Authorization of 12 months may be granted for subsequent treatment of KRAS G12C-mutated advanced or metastatic small bowel adenocarcinoma, as a single agent or in combination with cetuximab (Erbix) or panitumumab (Vectibix).

Appendiceal Neoplasms and Cancers²

Authorization of 12 months may be granted for subsequent treatment of KRAS G12C-mutated recurrent, progressive, or metastatic appendiceal neoplasms and cancers, as a single agent or in combination with cetuximab (Erbix) or panitumumab (Vectibix).

Continuation of Therapy

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

References

1. Lumakras [package insert]. Thousand Oaks, CA: Amgen Inc.; January 2025.
2. The NCCN Drugs & Biologics Compendium® © 2026 National Comprehensive Cancer Network, Inc. Available at: <https://www.nccn.org>. Accessed March 17, 2026.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Anal Carcinoma. Version 1.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/anal.pdf. Accessed March 5, 2026.