VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Lumakras Prior Authorization Policy
- Lumakras™ (sotorasib tablets – Amgen)

REVIEW DATE: 06/26/2024; selected revision 01/29/2025

OVERVIEW

Lumakras, a kirsten rat sarcoma (KRAS) inhibitor, is indicated for the following:[1]

- **Non-small cell lung cancer (NSCLC):** Treatment of *KRAS G12C*-mutated locally advanced or metastatic NSCLC, as determined by an FDA-approved test, in adults who have received at least one prior systemic therapy.
- **Colorectal cancer:** Treatment in combination with Vectibix® (panitumumab intravenous infusion) for *KRAS G12C*-mutated metastatic colorectal cancer, as determined by an FDA-approved test, in adults who have received prior fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.

The NSCLC indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Mutations in the *KRAS* gene most commonly occur at codon 12.[2] Data suggest that approximately 25% of patients with adenocarcinomas in a North American population have *KRAS* mutations. The prognosis of survival of patients with tumors with *KRAS* mutation is poorer compared with that of patients with tumors without *KRAS* mutation.

Guidelines

Lumakras is discussed in guidelines from the National Comprehensive Cancer Network (NCCN):

- **Ampullary Adenocarcinoma:** NCCN guidelines (version 1.2024 – December 13, 2023) recommend Lumakras as an option for disease progression after first line therapy in *KRAS G12C* mutation-positive tumors (category 2A).
- **Colon and Rectal Cancer:** Guidelines for colon cancer (version 6.2024 – January 17, 2025) and rectal cancer (version 5.2024 – January 17, 2025) recommend Lumakras for some situations in patients with *KRAS G12C*-mutated disease.[4,5] For initial treatment in combination with Erbitux® (cetuximab intravenous infusion) or Vectibix® (panitumumab intravenous infusion) after previous FOLFOX (5-FU, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) within past 12 months or as monotherapy if patient is unable to tolerate Erbitux or Vectibix due to toxicity (category 2A). Lumakras is also recommended as subsequent therapy after previous chemotherapy [category 2A].
- **Non-Small Cell Lung Cancer:** NCCN guidelines (version 3.2023 – April 13, 2023) recommend Lumakras as a subsequent therapy for patients with metastatic NSCLC with the *KRAS G12C* mutation (category 2A) who have been previously treated with combination chemotherapy regimens (± immunotherapy).[2]
- **Pancreatic Adenocarcinoma:** NCCN guidelines (version 1.2023 – May 4, 2023) recommend Lumakras as a subsequent therapy (category 2A) under "useful in certain circumstances" for locally advanced or metastatic disease. It is also recommended therapy for local recurrence in the pancreatic operative bed after resection (category 2A).[3]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Lumakras. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Lumakras is recommended in those who meet one of the following criteria:

FDA-Approved Indication

1. **Non-Small Cell Lung Cancer (NSCLC).** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has *KRAS G12C*-mutated locally advanced or metastatic NSCLC, as determined by an approved test; AND
   - **C)** Patient has been previously treated with at least one systemic regimen.
     Note: Examples of systemic regimens include those containing one or more of the following products: Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), Tecentriq (atezolizumab intravenous infusion), Alimta (pemetrexed intravenous infusion), Yervoy (ipilimumab intravenous infusion), Abraxane (albumin-bound paclitaxel intravenous infusion), bevacizumab, cisplatin, carboplatin, docetaxel, gemcitabine, paclitaxel, vinorelbine.

2. **Colon or Rectal Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has advanced or metastatic disease; AND
   - **C)** Patient has *KRAS G12C* mutation-positive disease; AND
   - **D)** Patient meets ONE of the following (i or ii):
     - **i.** The medication is used in combination with Erbitux (cetuximab intravenous infusion) or Vectibix (panitumumab intravenous infusion); OR
     - **ii.** As per the prescriber, the patient is unable to tolerate combination therapy; AND
   - **E)** Patient has previously received a chemotherapy regimen for colon or rectal cancer.
     Note: Examples of chemotherapy regimens include a fluoropyrimidine such as 5-fluorouracil (5-FU), capecitabine; oxaliplatin, irinotecan, or an adjunctive chemotherapy regimen such as FOLFOX (5-FU, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin).

Other Uses with Supportive Evidence

3. **Ampullary Adenocarcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has *KRAS G12C*-mutated disease, as determined by an approved test; AND
   - **C)** The medication is used as subsequent therapy.

4. **Pancreatic Adenocarcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND

B) Patient has *KRAS G12C*-mutated disease, as determined by an approved test; AND
C) Patient meets ONE of the following (i or ii):
  i. Patient meets BOTH of the following (a and b):
    a) Patient has locally advanced or metastatic disease; AND
    b) Patient has been previously treated with at least one systemic regimen; OR
    Note: Examples of systemic regimens include one or more of the following: gemcitabine, albumin-bound paclitaxel, capecitabine, Keytruda (pembrolizumab intravenous infusion), FOLFIRINOX (5-fluoruracil + leucovorin + irinotecan + oxaliplatin).
  ii. Patient has recurrent disease after resection.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Lumakras is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Lumakras™ tablets [prescribing information]. Thousand Oaks, CA: Amgen; January 2025.
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 3.2023 – April 13, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 12, 2023.
3. The NCCN Pancreatic Adenocarcinoma Clinical Practice Guidelines in Oncology (version 1.2023 – May 4, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 12, 2023.
4. The NCCN Ampullary Adenocarcinoma Clinical Practice Guidelines in Oncology (version 1.2024 – December 13, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 24, 2024.
5. The NCCN Colon Cancer Clinical Practice Guidelines in Oncology (version 6.2024 – January 17, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org/. Accessed on January 27, 2025.
6. The NCCN Rectal Cancer Clinical Practice Guidelines in Oncology (version 5.2024 – January 17, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org/. Accessed on January 27, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Pancreatic Adenocarcinoma:** Added new condition of approval and criteria based on guideline recommendations.	06/14/2023
Annual Revision	**Ampullary Adenocarcinoma:** Added new condition of approval and criteria based on guidelines. **Colon or Rectal Cancer:** Added new condition of approval and criteria based on guidelines.	06/26/2024
Selected Revision	**Colon or Rectal Cancer:** Moved this indication from Other Uses with Supportive Evidence to FDA-Approved Indication. Deleted "unresectable" disease qualifier. For criterion referring to combination regimen, deleted Note with examples and instead specified within criteria "…used in combination with Erbitux (cetuximab intravenous infusion) or Vectibix (panitumumab intravenous infusion)".	01/29/2025