

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Lumakras Prior Authorization Policy

- Lumakras™ (sotorasib tablets – Amgen)

REVIEW DATE: 06/26/2024

OVERVIEW

Lumakras, a Kirsten rat sarcoma (*KRAS*) inhibitor, is indicated for the treatment of adults 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.¹

This 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 3.2024 – May 24, 2024) and rectal cancer (version 2.2024 – April 30, 2024) 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) 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 therapy with oxaliplatin, irinotecan, FOLFOX (5-FU, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) [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.

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Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Lumakras is recommended in those who meet 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.

Other Uses with Supportive Evidence

2. **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.
3. **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 unresectable, 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 prescribed as part of a combination regimen for colon or rectal cancer; OR
Note: Examples of combination regimens include Lumakras + Erbitux (cetuximab intravenous infusion), Lumakras + Vectibix (panitumumab intravenous infusion).
 - 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).
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; April 2023.
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 3.2024 – May 24, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org/>. Accessed on June 24, 2024.
6. The NCCN Rectal Cancer Clinical Practice Guidelines in Oncology (version 2.2024 – April 30, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org/>. Accessed on June 24, 2024.