PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 06/14/2023

INSTRUCTIONS FOR USE

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CIGNA NATIONAL FORMULARY COVERAGE:

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):

- **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.

- **Lumakras™ (sotorasib tablets (Amgen)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Non-Small Cell Lung Cancer (NSCLC).** Approve for 1 year if the patient meets the following criteria (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. **Pancreatic Adenocarcinoma.** Approve for 1 year if the patient meets the following criteria (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 COVERED

- **Lumakras™ (sotorasib tablets (Amgen)**

is(are) considered experimental, investigational or unproven for ANY other use(s).

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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Non-Small Cell Lung Cancer (NCSLC):** For the test requirement, changed "FDA-approved test" to "approved test" – Patient has *KRAS G12C*-mutated locally advanced or metastatic NSCLC, as determined by an approved test. Approval duration was changed from 3 years to 1 year.	06/29/2022
Annual Revision	**Pancreatic Adenocarcinoma:** Added new condition of approval and criteria based on guideline recommendations**.**	06/14/2023