PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 06/29/2022

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

The National Comprehensive Network (NCCN) NSCLC guidelines (version 3.2022 – March 16, 2022) 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). The NCCN NSCLC guidelines note the following agents as initial systemic options for the treatment of advanced or metastatic NSCLC:

- **Performance status 0 to 1**: Preferred therapies, category 1: Keytruda/Alimta (pemetrexed intravenous infusion)/carboplatin or cisplatin; Other recommended therapies: Tecentriq/carboplatin/paclitaxel/bevacizumab (category 1); Tecentriq/carboplatin/Abraxane (albumin-bound paclitaxel intravenous infusion) [category 2A]; Opdivo/Yervoy (ipilimumab intravenous infusion) [category 2A]; Opdivo/Yervoy/Alimta/carboplatin or cisplatin (category 1); Patients with contraindications to programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitors, therapies that may be useful in certain circumstances (category 1): Bevacizumab/carboplatin/paclitaxel; carboplatin or cisplatin/one of the following: docetaxel, etoposide, gemcitabine, paclitaxel, Alimta; carboplatin/Abraxane, gemcitabine/docetaxel or vinorelbine.
- **Performance status 2:** Preferred therapy, category 2A: carboplatin/Alimta; Other recommended therapies, category 2A: carboplatin/one of the following: Abraxane, docetaxel, etoposide, gemcitabine, paclitaxel; Therapies that are useful in certain circumstances, category 2A: Abraxane, docetaxel, gemcitabine, paclitaxel, Alimta, gemcitabine/docetaxel, gemcitabine/vinorelbine.

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 the following criteria:

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.

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; May 2021.
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 3.2022 – March 16, 2022). © 2022 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on June 3, 2022.