Commercial PA Criteria

Effective: September 14, 2021

Prior Authorization: Lumakras

Products Affected: Lumakras (sotorasib) oral tablets

Medication Description: 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. 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).

Covered Uses: 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.

Exclusion Criteria: None

Required Medical Information:
1. Diagnosis
2. Previous therapies tried and failed

Age Restrictions: 18 years of age and older

Prescriber Restrictions: Prescribed by, or in consultation with, an oncologist.

Coverage Duration: 12 months

Other Criteria:

I. Initial Approval Criteria

1. Non-Small Cell Lung Cancer (NSCLC). Approve for 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.

II. Continued Therapy

1. Non-Small Cell Lung Cancer (NSCLC)
   A. Patient is responding positively to the therapy, demonstrated by stabilization of the disease; **AND**
   B. Patient has not experienced unacceptable toxicity from the drug

Quantity Limit: 960 mg daily for 30 days

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.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	9/14/2021
2	Update	QL changed from 240 tablets/30 days to 960mg/day for 30 days	All	12/26/2024