Commercial/Healthcare Exchange 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)

A. Patient has KRAS G12C-mutated locally advanced or metastatic NSCLC, as determined by an FDA-approved test; AND
B. 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 for intravenous [IV] infusion), Opdivo (nivolumab for IV infusion), Tecentriq (atezolizumab for IV infusion), Alimta (pemetrexed for IV infusion), Yervoy (ipilimumab for IV infusion), Abraxane (albumin-bound paclitaxel for IV 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: 240 tablets for 30 days

References:

1. Lumakras™ tablets [prescribing information]. Thousand Oaks, CA: Amgen; May 2021.
2. The NCCN Non-Small Cell Ung Cancer Cancers Clinical Practice Guidelines in Oncology (version 5.2021 – June 15, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on June 15, 2021.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	9/14/2021