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Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	June 25, 2021
Subject:	Lumakras	**Page:**	1 of 4

Last Review Date: March 8, 2024

Lumakras

Description

Lumakras (sotorasib)

Background
Lumakras (sotorasib) is an inhibitor of $KRAS^{G12C}$, a tumor-restricted, mutant-oncogenic form of the RAS GTPase, KRAS. Lumakras forms an irreversible, covalent bond with the unique cysteine of $KRAS^{G12C}$, locking the protein in an inactive state that prevents downstream signaling without affecting wild-type KRAS. Lumakras blocks KRAS signaling, inhibits cell growth, and promotes apoptosis only in *KRAS G12C* tumor cell lines (1).

Regulatory Status
FDA-approved indication: Lumakras is an inhibitor of the RAS GTPase family indicated for the 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 (1).

Lumakras has warnings regarding hepatotoxicity and interstitial lung disease (ILD)/pneumonitis. Liber function tests (ALT, AST, and total bilirubin) should be monitored prior to the start of Lumakras, every 3 weeks for the first 3 months of treatment, then once a month or as clinically indicated (1).

The safety and effectiveness of Lumakras in pediatric patients less than 18 years of age have not been established (1).

Related policies

Krazati

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Lumakras may be considered **medically necessary** if the conditions indicated below are met.

Lumakras may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Locally advanced or metastatic non-small cell lung cancer (NSCLC)

AND ALL of the following:

1. Presence of *KRAS G12C* mutation as determined by an FDA-approved test
2. Patient has received at least one prior systemic therapy
3. Prescriber agrees to monitor AST, ALT, and total bilirubin

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Locally advanced or metastatic non-small cell lung cancer (NSCLC)

AND ALL of the following:

1. **NO** disease progression or unacceptable toxicity
2. Prescriber agrees to monitor AST, ALT, and total bilirubin

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Strength	Quantity
120 mg	960 mg per day
320 mg	

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Lumakras (sotorasib) is an inhibitor of the RAS GTPase family indicated for the treatment of adult patients with *KRAS G12C*-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC). Lumakras has warnings regarding hepatotoxicity and interstitial lung disease (ILD)/pneumonitis. The safety and effectiveness of Lumakras in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Lumakras while maintaining optimal therapeutic outcomes.

References

1. Lumakras [package insert]. Thousand Oaks, CA: Amgen Inc.; April 2023.
2. NCCN Drugs & Biologics Compendium® Sotorasib 2024. National Comprehensive Cancer Network, Inc. Accessed on January 16, 2024.

Policy History

Date	Action
June 2021	Addition to PA
September 2021	Annual review and reference update
March 2022	Annual review and reference update

February 2023	Addition of new strength 320 mg tablet and revised quantity chart to 960 mg per day
March 2023	Annual review and reference update
March 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.