UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1360-4
Program	Prior Authorization/Notification
Medication	Lumakras™ (sotorasib)
P&T Approval Date	7/2021, 7/2022, 7/2023, 7/2024
Effective Date	10/1/2024

1. Background:

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) who have received at least one prior systemic therapy. The National Comprehensive Cancer Network (NCCN) recommends the use of Lumakras as subsequent therapy for the treatment of *KRAS G12C*-mutated recurrent, advanced, or metastatic NSCLC.

NCCN also recommends the use of Lumakras as subsequent therapy for the treatment of *KRAS G12C*-mutated pancreatic adenocarcinoma, ampullary adenocarcinoma, colon cancer, and rectal cancer.

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. <u>Patients less than 19 years of age</u>

1. **Lumakras** will be approved based on the following criterion:

   a. Member is less than 19 years of age

   Authorization will be issued for 12 months.

B. <u>Non-Small Cell Lung Cancer (NSCLC)</u>

1. **<u>Initial Authorization</u>**

   a. **Lumakras** will be approved based on **<u>all</u>** of the following criteria:

      (1) Diagnosis of non-small cell lung cancer (NSCLC)

-AND-

(2) Disease is **one** of the following:

(a) Recurrent
(b) Advanced
(c) Metastatic

-AND-

(3) Tumor is KRAS G12C-mutated

-AND-

(4) Patient has received at least one prior systemic therapy (e.g., immune checkpoint inhibitor, platinum-based chemotherapy)

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Lumakras** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Lumakras therapy

Authorization will be issued for 12 months.

C. Pancreatic Adenocarcinoma

1. **Initial Authorization**

a. **Lumakras** will be approved based on **all** of the following criteria:

(1) Diagnosis of pancreatic adenocarcinoma

-AND-

(2) Disease is **one** of the following:

(a) Recurrent
(b) Advanced
(c) Metastatic

-AND-

(3) Tumor is KRAS G12C-mutated

-AND-

(4) Patient has received at least one prior systemic therapy (e.g., immune checkpoint inhibitor, platinum-based chemotherapy)

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Lumakras** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Lumakras therapy

Authorization will be issued for 12 months.

D. Ampullary Adenocarcinoma

1. **Initial Authorization**

a. **Lumakras** will be approved based on **all** of the following criteria:

(1) Diagnosis of ampullary adenocarcinoma

-AND-

(2) Disease is **one** of the following:

(a) Recurrent
(b) Advanced
(c) Metastatic

-AND-

(3) Tumor is KRAS G12C-mutation positive

-AND-

(4) Patient has received at least one prior systemic therapy (e.g., immune checkpoint inhibitor, platinum-based chemotherapy)

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Lumakras** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Lumakras therapy

Authorization will be issued for 12 months.

E. Colorectal Cancer

1. **Initial Authorization**

   a. **Lumakras** will be approved based on **all** of the following criteria:

      (1) Diagnosis of **one** of the following:

         (a) Colon Cancer
         (b) Rectal Cancer

-AND-

      (2) Disease is **one** of the following:

         (a) Recurrent
         (b) Advanced
         (c) Metastatic

-AND-

      (3) Tumor is KRAS G12C-mutation positive

-AND-

      (4) Patient has received at least one prior systemic therapy (e.g., immune checkpoint inhibitor, platinum-based chemotherapy)

      Authorization will be issued for 12 months.

2. **Reauthorization**

   a. **Lumakras** will be approved based on the following criterion:

      (1) Patient does not show evidence of progressive disease while on Lumakras therapy

      Authorization will be issued for 12 months.

F. NCCN Recommended Regimens

a. The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Lumakras [package insert]. Thousand Oaks, CA: Amgen, Inc; April 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. May 16, 2024.

Program	Prior Authorization/Notification – Lumakras (sotorasib)
Change Control	
7/2021	New program.
7/2022	Annual review. Expanded coverage criteria to include "recurrent" disease per current NCCN guidelines. Added state mandate disclaimer and updated references.
7/2023	Annual review. Updated background and criteria to include coverage of pancreatic adenocarcinoma per NCCN guidelines. Updated references.
7/2024	Annual review. Added criteria for ampullary adenocarcinoma, colon cancer, and rectal cancer per NCCN guidelines. Updated background and references.