

Lumakras (sotorasib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Lumakras (sotorasib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Lumakras (sotorasib) may be approved if the following criteria are met:

- I. Individual has a diagnosis of locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) (label, NCCN 2A); **AND**
 - II. Individual is using as monotherapy; **AND**
 - III. Individual has confirmed disease progression after one or more prior lines of systemic therapy; **AND**
 - IV. Individual has *KRAS G12C*-mutation;
- OR**
- V. Individual has a diagnosis of locally advanced, metastatic or recurrent pancreatic disease (NCCN 2A); **AND**
 - VI. Individual is using as monotherapy and previously has not used Lumakras (sotorasib); **AND**
 - VII. Has an Eastern Cooperative Oncology Group (ECOG) performance status of 0-2; **AND**
 - VIII. Using as subsequent therapy; **AND**
 - IX. Individual has *KRAS G12C*-mutation.

Key References:

1. Clinical Pharmacology powered by ClinicalKey. Tampa (FL): Elsevier. 2023. Available from: <http://www.clinicalkey.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: July 3, 2023.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on July 3, 2023
 - a. Non-Small Cell Lung Cancer. V3.2023. Revised April 13, 2023.
 - b. Pancreatic Adenocarcinoma. V2.2023. Revised June 19, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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