Lumakras® (sotorasib)
(Oral)

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I. Length of Authorization

Coverage will be provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Lumakras 120 mg tablets: 8 tablets per day
- Lumakras 240 mg tablets: 4 tablets per day
- Lumakras 320 mg tablets: 3 tablets per day

B. Max Units (per dose and over time) [HCPCS Unit]:

- 960 mg per day

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- Patient has not previously received KRAS G12C-targeted therapy (i.e., adagrasib); **AND**

Universal Criteria [1]

- Patient does not have suspected or confirmed interstitial lung disease (ILD) or pneumonitis; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with gastric acid-reducing agents (i.e., PPIs, H_2 receptor antagonists, and locally acting antacids), or if acid-reducing therapy is unavoidable, administer locally acting antacids at appropriately spaced administration times from sotorasib; **AND**
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**

- Patient has *KRAS G12C* mutation positive disease as detected by an FDA-approved or CLIA compliant test❖; **AND**

Non-Small Cell Lung Cancer (NSCLC) † ‡ Φ [1,2]

- Patient has recurrent, advanced, or metastatic disease *(excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease)* or mediastinal lymph node recurrence with prior radiation therapy; **AND**
- Used as a single agent as subsequent therapy

Ampullary Adenocarcinoma ‡ [2]

- Used as a single agent as subsequent therapy for disease progression

Pancreatic Adenocarcinoma ‡ [2]

- Used as a single agent; **AND**
  - Used as subsequent therapy for locally advanced or metastatic disease that has progressed; **AND**
    - Patient has good performance status (defined as ECOG PS 0-1, with good biliary drainage and adequate nutritional intake) or intermediate PS (ECOG PS 2); **OR**
  - Used as alternative systemic therapy, if not previously used, for patients with good performance status (ECOG PS 0-1) or intermediate PS (ECOG PS 2); **AND**
    - Patient has local recurrence in the pancreatic operative bed after resection; **OR**
    - Patient has recurrent metastatic disease with or without local recurrence after resection

Colorectal Cancer ‡ [2]

- Used as initial treatment for unresectable metastatic disease and previous FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) within the past 12 months; **AND**
  - Will not be used as part of an adjuvant treatment regimen; **AND**
  - Used in combination with cetuximab or panitumumab OR as a single agent for patients unable to tolerate an EGFR-inhibitor due to toxicity; **AND**
  - Patient has mismatch repair proficient/microsatellite-stable (pMMR/MSS) disease; **OR**
- Used as subsequent therapy for progression of advanced or metastatic disease; **AND**
  - Used in combination with cetuximab or panitumumab, if not previously given, OR as a single agent for patients unable to tolerate an EGFR-inhibitor due to toxicity; **AND**
    - Patient has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease; **OR**
    - Patient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease or polymerase epsilon/delta [POLE/POLD1] mutation; **AND**

- Patient is not eligible for or has progressed on checkpoint inhibitor immunotherapy

Appendiceal Adenocarcinoma – Colon Cancer ‡ [2]

- Used as subsequent therapy for progression of advanced or metastatic disease; **AND**
- Used in combination with cetuximab or panitumumab, if not previously given; **AND**
  - Patient has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease; **OR**
  - Patient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease or polymerase epsilon/delta (POLE/POLD1) mutation; **AND**
    - Patient is not eligible for or has progressed on checkpoint inhibitor immunotherapy

❖*If confirmed using an FDA approved assay - http://www.fda.gov/companiondiagnostics*

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1]

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in Section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: interstitial lung disease/pneumonitis, hepatotoxicity, etc.; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

V. Dosage/Administration [1,6-13]

Indication	Dose
NSCLC	Administer 960 mg (eight 120 mg tablets, four 240 mg tablets, or three 320 mg tablets) orally once daily until disease progression or unacceptable toxicity. ***Note:** Select patients for treatment of locally advanced or metastatic NSCLC with Lumakras based on the presence of KRAS G12C mutation in tumor or plasma specimens. If no mutation is detected in a plasma specimen, test tumor tissue.*
All other indications	Administer 960 mg (eight 120 mg tablets, four 240 mg tablets, or three 320 mg tablets) orally once daily until disease progression or unacceptable toxicity.

VI. Billing Code/Availability Information

HCPCS Code(s):

- J8999 – Prescription drug, oral, chemotherapeutic, nos
- C9399 – Unclassified drugs or biologicals

NDC(s):

- Lumakras 120 mg tablets: 55513-0488-xx
- Lumakras 240 mg tablets: 55513-0512-xx
- Lumakras 320 mg tablets: 55513-0504-xx

VII. References

1. Lumakras [package insert]. Thousand Oaks, CA; Amgen, Inc; June 2024. Accessed July 2024.
2. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) sotorasib. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed July 2024.
3. Hong DS, Fakih MG, Strickler JH, et al. KRAS(G12C) Inhibition with Sotorasib in Advanced Solid Tumors. N Engl J Med. 2020 Sep 24;383(13):1207-1217. doi: 10.1056/NEJMoa1917239. Epub 2020 Sep 20.
4. Kuboki Y, Yaeger R, Fakih MG, et al. Sotorasib in combination with panitumumab in refractory KRAS G12C-mutated colorectal cancer: Safety and efficacy for phase Ib full expansion cohort. Ann Oncol 2022;33:S136-S196
5. Strickler JH, Satake H, George TJ, et al. Sotorasib in KRAS p.G12C-Mutated Advanced Pancreatic Cancer. N Engl J Med. 2023 Jan 5;388(1):33-43.
6. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Sotorasib: Ampullary Adenocarcinoma Chemotherapy Order Template, AMP34. National Comprehensive Cancer Network, 2024. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed July 2024.
7. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Colon Cancer Version 4.2024. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed July 2024.
8. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Rectal Cancer Version 3.2024. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network,

Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed July 2024.

9. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Sotorasib: Pancreatic Adenocarcinoma Chemotherapy Order Template, PAN55. National Comprehensive Cancer Network, 2024. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed July 2024.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C18.0	Malignant neoplasm of cecum
C18.1	Malignant neoplasm of appendix
C18.2	Malignant neoplasm of ascending colon
C18.3	Malignant neoplasm of hepatic flexure
C18.4	Malignant neoplasm of transverse colon
C18.5	Malignant neoplasm of splenic flexure
C18.6	Malignant neoplasm of descending colon
C18.7	Malignant neoplasm of sigmoid colon
C18.8	Malignant neoplasm of overlapping sites of colon
C18.9	Malignant neoplasm of colon, unspecified
C19	Malignant neoplasm of rectosigmoid junction
C20	Malignant neoplasm of rectum
C21.8	Malignant neoplasm of overlapping sites of rectum, anus and anal canal
C24.1	Malignant neoplasm of ampulla of Vater
C25.0	Malignant neoplasm of head of pancreas
C25.1	Malignant neoplasm of body of pancreas
C25.2	Malignant neoplasm of tail of pancreas
C25.3	Malignant neoplasm of pancreatic duct
C25.7	Malignant neoplasm of other parts of pancreas
C25.8	Malignant neoplasm of overlapping sites of pancreas
C25.9	Malignant neoplasm of pancreas, unspecified
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung

C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C78.00	Secondary malignant neoplasm of unspecified lung
C78.01	Secondary malignant neoplasm of right lung
C78.02	Secondary malignant neoplasm of left lung
C78.6	Secondary malignant neoplasm of retroperitoneum and peritoneum
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct
Z85.038	Other malignant neoplasm of large intestine
Z85.07	Personal history of malignant neoplasm of pancreas
Z85.09	Personal history of malignant neoplasm of other digestive organs
Z85.118	Personal history of other malignant neoplasm of bronchus and lung

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC