Exkivity™ (mobocertinib)
(Oral)

Document Number: IH-0623

Last Review Date: 05/04/2023
Date of Origin: 10/01/2021
Dates Reviewed: 10/2021, 05/2022, 05/2023

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]:

- Exkivity 40 mg capsules: 4 capsules daily

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

- 160 mg daily

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient has tried and failed or has a contraindication to therapy with Rybrevant (amivantamab-vmjw); **AND**

- Patient is at least 18 years of age; **AND**

Universal Criteria [1]

- Patient does not have untreated brain metastases (clinically stable asymptomatic brain metastases are allowed); **AND**
- Patient does not have a history of interstitial lung disease, radiation pneumonitis that required steroid treatment, or drug-related pneumonitis; **AND**
- Left ventricular ejection fraction (LVEF) is measured prior to initiating therapy and will be assessed at regular intervals during treatment; **AND**
- Patient does not have prolonged QTc interval; **AND**
- Patient is not currently being treated with medications known to be associated with the development of Torsades de Pointes; **AND**
- Will not be used in combination with amivantamab; **AND**
- Patient will avoid concomitant therapy with any of the following:

- Coadministration with drugs that prolong the QTc interval (e.g., amiodarone, ciprofloxacin, quetiapine, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Coadministration with strong or moderate CYP3A inhibitors (e.g., fluconazole, itraconazole, ketoconazole, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Coadministration with strong and moderate CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, efavirenz, etc.); **AND**

Non-Small Cell Lung Cancer (NSCLC) † Φ [1-4]

- Used as single agent therapy; **AND**
- Used for 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**
- Patient has epidermal growth factor receptor (EGFR) exon 20 insertion mutation positive disease as detected by an FDA-approved or CLIA compliant test❖; **AND**
- Used as subsequent therapy if not previously received

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

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

IV. Renewal Criteria [1]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: interstitial lung disease (ILD)/pneumonitis, cardiac toxicity (e.g., grade ≥2 decreased ejection fraction, cardiomyopathy, congestive heart failure, etc.), QT interval prolongation, Torsades de Pointes, severe diarrhea (grade ≥2), etc.

V. Dosage/Administration [1]

Indication	Dose
NSCLC	Administer 160 mg orally once daily, with or without food until disease progression or unacceptable toxicity.

VI. Billing Code/Availability Information

HCPCS Code:

- J8999: Prescription drug, oral, chemotherapeutic, Not Otherwise Specified
- C9399: Unclassified drugs or biologicals *(Hospital Outpatient use only)*

NDC:

- Exkivity 40 mg capsules: 63020-0040-xx

VII. References

1. Exkivity [package insert]. Lexington, MA; Takeda Pharm., Inc.; March 2023. Accessed March 2023.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for mobocertinib. National Comprehensive Cancer Network, 2023. 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 March 2023.
3. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Non-Small Cell Lung Cancer, Version 2.2023. National Comprehensive Cancer Network, 2023. 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 March 2023.
4. Riely GJ, Neal JW, Camidge DR, et al. Activity and Safety of Mobocertinib (TAK-788) in Previously Treated Non-Small Cell Lung Cancer with EGFR Exon 20 Insertion Mutations from a Phase I/II Trial. Cancer Discov. 2021 Jul;11(7):1688-1699. doi: 10.1158/2159-8290.CD-20-1598. Epub 2021 Feb 25.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
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

ICD-10	ICD-10 Description
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
Z85.118	Personal history of other malignant neoplasm of bronchus and lung

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

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 Determination (NCD), Local Coverage Determinations (LCDs) and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/Medicare-Coverage-Database/search.aspx. Additional indications may be covered 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)
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, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
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