Clinical Policy Title:	mobocertinib
Policy Number:	RxA.704
Drug(s) Applied:	Exkivity™
Original Policy Date:	12/07/2021
Last Review Date:	12/07/2021
Line of Business Policy Applies to:	All lines of business

Background

Mobocertinib (Exkivity™) is a kinase inhibitor indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
mobocertinib (Exkivity™)	Locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations	160 mg orally once daily	160 mg/day

Dosage Forms

- Capsules: 40 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Advanced or metastatic NSCLC (must meet all)**:**

1. Diagnosis of locally advanced, recurrent or metastatic NSCLC with EGFR exon 20 insertion mutation as detected by an FDA-approved test;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease has progressed on or after platinum-based chemotherapy (eg carboplatin, cisplatin);
5. Patient's ECOG performance status is 0-1;
6. Requested dose does not exceed 160 mg orally once daily.

Approval Duration

Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. All indication in section I (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed 160 mg orally once daily;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

*Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
NSCLC: non-small cell lung cancer
EGFR: epidermal growth factor receptor
FDA: Food and Drug Administration
NCCN: National Comprehensive Cancer Network
ECOG: Eastern Oncology Cooperative Group

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Rybrevant™	Body Weight: Less than 80 kg- 1050 mg intravenously. Greater than or equal to 80 kg: 1400 mg intravenously.	Weight of less than 80 kg: 1,050 mg intravenously. Weight of 80 kg or more: 1,400 mg intravenously
Tarceva® (erlotinib)		
Iressa®		
Gilotrif®		
Tagrisso®		
Vizimpro		

Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand, Brand name® when the drug is available by brand only and generic name when the drug is available by generic only.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None reported.

- Boxed Warning(s):
  - QTc prolongation and Torsades de pointes.

APPENDIX D: General Information

1. Patients in the clinical study were screened for abnormal QT. All patients were required to have a normal QT on an echocardiogram (ECG), which was defined as QT interval corrected (Fridericia) (QTcF) of ≤450 milliseconds (ms) in males or ≤470 ms in females.
2. Patients with a history of interstitial lung disease, drug-related pneumonitis, or radiation pneumonitis that required steroid treatment; significant, uncontrolled, active cardiovascular disease; or prolonged QTc interval were excluded from enrollment in this trial.
3. Interstitial Lung Disease (ILD)/Pneumonitis: Monitor patients for new or worsening pulmonary symptoms indicative of ILD/pneumonitis. Immediately withhold Exkivity™ in patients with suspected ILD /pneumonitis and permanently discontinue Exkivity™ if ILD/pneumonitis is confirmed.
4. Cardiac Toxicity: Monitor cardiac function, including left ventricular ejection fraction, at baseline and during treatment. Withhold, resume at reduced dose or permanently discontinue based on severity.
5. Diarrhea: Diarrhea may lead to dehydration or electrolyte imbalance, with or without renal impairment. Monitor electrolytes and advise patients to start an antidiarrheal agent at first episode of diarrhea and to increase fluid and electrolyte intake. Withhold, reduce the dose, or permanently discontinue Exkivity™ based on the severity.
6. Embryo-Fetal Toxicity: Can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective non-hormonal contraception.

- ECOG Performance Status Index:

Grade	ECOG Performance Status
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours
3	Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
4	Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
5	Dead

References

1. Exkivity™ prescribing information. Lexington, MA: Takeda Pharmaceuticals America, Inc: September 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215310s000lbl.pdf. Accessed October 6, 2021.
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3. IPD Analytics Rx Insights_New Drug Approval Review_ Trudhesa™ _09 2021. Accessed with subscription at: https://secure.ipdanalytics.com/User/Pharma/RxStrategy/Search?q=Exkivity. Accessed October 6, 2021.

4. National Comprehensive Cancer Network Guidelines. Non-small cell lung cancer Version 6.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed October 6, 2021.
5. Mobocertinib, Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed with subscription at: http://online.lexi.com. Accessed October 4, 2021.
6. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed October 6, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	12/07/2021	12/07/2021