Reference number(s)
4941-A

SPECIALTY GUIDELINE MANAGEMENT

EXKIVITY (mobocertinib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication
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.

B. Compendial Use
Non-small cell lung cancer

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: test results showing the presence of EGFR exon 20 insertion mutations

III. CRITERIA FOR INITIAL APPROVAL

Non-Small Cell Lung Cancer (NSCLC)
Authorization of 12 months may be granted for treatment of NSCLC when all of the following criteria are met:
1. Member has locally advanced, recurrent, or metastatic disease
2. Member has EGFR exon 20 insertion mutations
3. Disease has progressed on or after platinum-based chemotherapy
4. The requested medication is used as a single agent

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Exkivity [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc; March 2023.
2. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed July 6, 2023.