PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Exkivity Prior Authorization Policy
- Exkivity™ (mobocertinib capsules – Takeda)

REVIEW DATE: 09/11/2024

OVERVIEW

Exkivity, an epidermal growth factor receptor (*EGFR*) inhibitor, is indicated for the treatment of adults with locally advanced or metastatic **non-small cell lung cancer (NSCLC)** with *EGFR* exon 20 insertion mutation, as determined by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy.

Exkivity received accelerated approval for this indication in 2021; however, the drug has failed to meet its primary endpoint in its Phase III confirmatory study. Exkivity was withdrawn from the US market in April 2024.[3] Patients who were initiated on Exkivity therapy prior to April 1, 2024 will continue to have access to the drug through the Takeda Compassionate Use program.

Guidelines

The National Comprehensive Cancer Network (NCCN) NSCLC guidelines (version 9.2024 – September 9, 2024) no longer recommends Exkivity as a subsequent treatment option for patients with *EGFR* exon 20 insertion-positive metastatic NSCLC and disease progression on or after initial systemic therapy (category 2A recommendation).[2] Rybrevant™ (amivantamab-vmjw intravenous infusion) is the "Preferred" first-line therapy [category 1] for *EGFR* exon 20 insertion mutation.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Exkivity. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Exkivity is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Non-Small Cell Lung Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, E, and F):
   - **A)** Patient is currently receiving Exkivity; AND
   - **B)** Patient is ≥ 18 years of age; AND
   - **C)** Patient has locally advanced or metastatic disease; AND
   - **D)** Patient has epidermal growth factor receptor (*EGFR*) exon 20 insertion-positive disease; AND
   - **E)** The mutation was determined by an approved test; AND
   - **F)** Patient has previously tried at least one platinum-based chemotherapy.
     Note: Examples of platinum-based chemotherapy include carboplatin, cisplatin, and oxaliplatin.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Exkivity is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Exkivity™ capsules [prescribing information]. Lexington, MA: Takeda; March 2023.
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 9.2024 - September 9, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 9, 2024.
3. Takeda announces Exkivity (mobocertinib) is no longer commercially available in the US market. Takeda. April 10, 2024. Email from Takeda. Received April 10, 2024.