

## PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology – Exkivity Prior Authorization Policy

- Exkivity™ (mobocertinib capsules – Takeda)

**REVIEW DATE:** 09/21/2022

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### 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.

### Guidelines

The National Comprehensive Cancer Network (NCCN) NSCLC guidelines (version 4.2022 – September 2, 2022) recommend 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).<sup>2</sup> Platinum-based chemotherapy is typically recommended as first-line for most patients with *EGFR* exon 20 insertion-positive metastatic NSCLC. Exkivity is also recommended as a treatment option for patients who progressed on Rybrevant™ (amivantamab-vmjw intravenous infusion) [category 2A recommendation].

### 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 the following criteria (A, B, C, D, and E):
  - A) Patient is  $\geq 18$  years of age; AND
  - B) Patient has locally advanced or metastatic disease; AND
  - C) Patient has epidermal growth factor receptor (*EGFR*) exon 20 insertion-positive disease; AND
  - D) The mutation was determined by an approved test; AND
  - E) 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; September 2021.
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 4.2022 - September 2, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on September 15, 2022.