VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 09/22/2021

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. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

There is a Boxed Warning regarding the potential for Exkivity to cause life threatening heart rate-corrected QT (QTc) prolongation, including Torsades de Pointes. Patients should avoid concomitant use of drugs known to prolong the QTc interval and strong or moderate cytochrome (CYP)3A4 inhibitors.

Guidelines

The National Comprehensive Cancer Network (NCCN) NSCLC guidelines (version 6.2021 – September 30, 2021) recommend Exkivity as a subsequent treatment option for patients (with performance status 0 to 2) with advanced or metastatic NSCLC with *EGFR* exon 20 insertion mutations, whose disease has progressed on or after initial systemic treatment (category 2A recommendation).[2] 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 Indications

1. **Non-Small Cell Lung Cancer (NSCLC).** Approve for 3 years if the patient meets the following criteria (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has locally advanced or metastatic NSCLC; AND
   - **C)** Patient has epidermal growth factor receptor (EGFR) exon 20 insertion mutation, as determined by an approved test; AND
   - **D)** 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 6.2021 – September 30, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 1, 2021.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	09/22/2021
Update	10/01/20212: Updated Overview with updated NCCN NSCLC guideline recommendation (version 6.2021 – September 30, 2021).	--