# Commercial/Healthcare Exchange PA Criteria

***Effective: December 9, 2021***

***Prior Authorization:*** Exkivity™

***Products Affected:*** Exkivity™ (mobocertinib) oral capsules

***Medication Description:*** 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.

***Covered Uses:*** 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.

***Exclusion Criteria:*** None

***Required Medical Information:***

1. Diagnosis
2. Previous therapies tried and failed

***Age Restriction:*** 18 years of age and older

***Prescriber Restriction:*** Prescribed by, or in consultation with, an oncologist.

***Coverage Duration:*** 12 months

***Other Criteria:***

**I. Initial Approval Criteria**

**1. Non-Small Cell Lung Cancer (NSCLC).** Approve for one year if the patient meets the following criteria:

1. Patient is ≥ 18 years of age; **AND**
2. Patient has locally advanced or metastatic NSCLC; **AND**
3. Patient has epidermal growth factor receptor (EGFR) exon 20 insertion mutation, as determined by an approved test; **AND**
4. Patient has previously tried at least one platinum-based chemotherapy; **AND**
5. Prescribed by, or in consultation with, an oncologist.

**II. Continuation Criteria:**

1. Member has responded positively to the treatment as determined by the prescribing physician; **AND**
2. Member has not experienced unacceptable toxicity from the drug**.**

***References:***


1. EXKIVITY [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc. Revised 9/2021. Accessed 10/2021
2. EXKIVITY. IBM Micromedex® [database online]. Greenwood Village, CO. Truven Health Analytics. Available at: https://www.micromedexsolutions.com. Updated October 6, 2021. Accessed October 15, 2021.
3. UpToDate® Available at: www.uptodate.com. Systemic Therapy for Advanced Non Small cell Lung Cancer with an Activating Mutation in the Epidermal Growth Factor Receptor. Accessed on October 14, 2021.


***Policy Revision history***

| Rev # | Type of Change | Summary of Change | Sections Affected | Date |
|---|---|---|---|---|
| 1 | New Policy | New Policy | All | 12/9/2021 |