PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 09/13/2023; selected revision 10/11/2023

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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. Due to this, on October 2, 2023, the manufacturer announced the initiation of a voluntary withdrawal for Exkivity. The manufacturer noted that patients receiving Exkivity can continue to get access when the drug is withdrawn.

Guidelines

The National Comprehensive Cancer Network (NCCN) NSCLC guidelines (version 3.2023 – April 13, 2023) 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).[2] 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]. The

NCCN guidelines have not been updated to reflect Exkivity withdrawal from the market.

POLICY STATEMENT

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

- **Exkivity™ (mobocertinib capsules (Takeda)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Non-Small Cell Lung Cancer.** Approve for 1 year if the patient meets 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 COVERED

- **Exkivity™ (mobocertinib capsules (Takeda)**

is(are) considered experimental, investigational or unproven for ANY other use(s).

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 3.2023 - April 13, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 11, 2023.
3. Takeda to pull lung cancer med Exkivity around the world after confirmatory trial flop. Fierce Pharma. October 3, 2023. Available at: https://www.fiercepharma.com/pharma/takeda-pull-lung-cancer-med-exkivity-around-world-after-confirmatory-trial-flop. Accessed on October 6, 2023.
4. Important information about Exkivity (mobocertinib). Takeda. October 2, 2023. Available at: https://www.exkivity-update.com/. Accessed on October 6, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	09/21/2022
Annual Revision	No criteria changes	09/13/2023
Selected Revision	**Non-Small Cell Lung Cancer:** Due to withdrawal from the market, a requirement was added to limit approval to a patient who is currently receiving Exkivity.	10/11/2023