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Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	October 1, 2021
Subject:	Exkivity	**Page:**	1 of 5

Last Review Date: March 8, 2024

Exkivity

Description

Exkivity (mobocertinib)

Background
Exkivity (mobocertinib) is a kinase inhibitor of the epidermal growth factor receptor (EGFR) that covalently binds to and inhibits EGFR exon 20 insertion mutations. EGFR is a protein involved in the growth and spread of cancer cells that is detected in many human cancers, including lung cancer. In animal models, Exkivity demonstrated anti-tumor activity against xenografts with the EGFR exon 20 insertions (1).

Regulatory Status
FDA-approved indication: Exkivity is indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test whose disease has progressed on or after platinum-based chemotherapy (1).

Exkivity has a boxed warning regarding QT (QTc) prolongation and the possibility of Torsades de Pointes, a potentially fatal heart arrythmia. Patients should be monitored for QT prolongation, electrolytes at baseline and periodically during treatment. Concomitant administration with drugs that are known to prolong the QTc interval and strong or moderate CYP3A inhibitors should be avoided. If QT prolongation occurs, the dose of Exkivity should be reduced or permanently discontinued depending upon the severity of prolongation (1).

Exkivity has warnings regarding the following: interstitial lung disease (ILD)/pneumonitis, cardiac toxicity, diarrhea, and embryo-fetal toxicity (1).

Exkivity can cause fetal harm when administered in pregnant women. Pregnancy status in females of reproductive potential should be verified prior to initiating Exkivity. Females of reproductive potential should be advised to use effective non-hormonal contraception during treatment and for 1 month after the last dose of Exkivity. Males with female partners of reproductive potential should be advised to use effective contraception during treatment with Exkivity and for 1 week after the last dose (1).

The safety and effectiveness of Exkivity in pediatric patients have not been established (1).

Related policies
Erlotinib, Gilotrif, Iressa, Tagrisso, Vizimpro

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Exkivity may be considered **medically necessary** if the conditions indicated below are met.

Exkivity may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

1. Locally advanced or metastatic non-small cell lung cancer (NSCLC)
    a. EGFR exon 20 insertion mutation as detected by an FDA-approved test
    b. Disease has progressed on or after platinum-based chemotherapy

AND ALL of the following:

1. Prescriber agrees to monitor for QTc prolongation and risk factors for QTc prolongation before initiation of treatment and periodically during treatment
2. Female patients of reproductive potential **only**: pregnancy will be excluded before start of treatment and patient will be advised to use effective non-

hormonal contraception during treatment with Exkivity and for 1 month after the last dose
3. Male patients with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Exkivity and for 1 week after the last dose

Prior–Approval *Renewal* Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

1. Locally advanced or metastatic non-small cell lung cancer (NSCLC)
    a. EGFR exon 20 insertion mutation as detected by an FDA-approved test

AND ALL of the following:
1. **NO** disease progression or unacceptable toxicity
2. Prescriber agrees to monitor for QTc prolongation and risk factors for QTc prolongation periodically during treatment
3. Female patients of reproductive potential **only**: patient will be advised to use effective non-hormonal contraception during treatment with Exkivity and for 1 month after the last dose
4. Male patients with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Exkivity and for 1 week after the last dose

Policy Guidelines

Pre–PA Allowance
None

Prior–Approval Limits

Quantity

Drug	Quantity per 90 days
Exkivity 40mg	360 capsules

Duration 12 months

Prior–Approval *Renewal* Limits

Same as above

Rationale

Summary

Exkivity (mobocertinib) is a kinase inhibitor of the epidermal growth factor receptor (EGFR) that covalently binds to and inhibits EGFR exon 20 insertion mutations. It is indicated for the treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations. Exkivity has a boxed warning regarding QTc prolongation, and patients should be monitored for QTc prolongation and its risk factors at baseline and periodically during treatment. Exkivity has warnings regarding the following: interstitial lung disease (ILD)/pneumonitis, cardiac toxicity, diarrhea, and embryo-fetal toxicity. The safety and effectiveness of Exkivity in pediatric patients have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Exkivity while maintaining optimal therapeutic outcomes.

References

1. Exkivity [package insert]. Lexington, MA: Takeda Pharmaceutical America, Inc.; September 2023.
2. NCCN Drugs & Biologics Compendium® Mobocertinib 2024. National Comprehensive Cancer Network, Inc. Accessed on January 17, 2024.

Policy History

Date	Action
October 2021	Addition to PA

December 2021	Annual review and reference update
March 2022	Annual review and reference update
March 2023	Annual review and reference update
March 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.