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Section:	Prescription Drugs	**Effective Date:**	January 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	October 12, 2018
Subject:	Vizimpro	**Page:**	1 of 4

Last Review Date: December 8, 2023

Vizimpro

Description

Vizimpro (dacomitinib)

Background

Vizimpro (dacomitinib) is an irreversible inhibitor of the kinase activity of the human EGFR family (EGFR/HER1, HER2, and HER4) and certain EGFR activating mutations (exon 19 deletion or the exon 21 L858R substitution mutation). Vizimpro showed dose-dependent inhibition of EGFR and HER2 autophosphorylation and tumor growth in mice bearing subcutaneously implanted human tumor xenografts driven by HER family targets including mutated EGFR. Vizimpro also exhibited antitumor activity in orally-dosed mice bearing intracranial human tumor xenografts driven by EGFR amplifications (1).

Regulatory Status

FDA-approved indication: Vizimpro is a kinase inhibitor indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test (1).

Vizimpro can cause severe and fatal interstitial lung disease (ILD)/pneumonitis. Patients should be monitored for pulmonary symptoms indicative of ILD/pneumonitis. Vizimpro should be withheld in patients who present with worsening of respiratory symptoms which may be indicative of ILD (such as dyspnea, cough, and fever) (1).

Severe and fatal diarrhea may occur in patients treated with Vizimpro. Vizimpro should be withheld for Grade 2 or greater diarrhea until recover to less than or equal to Grade 1 severity,

then Vizimpro can be resumed at the same or a reduced dose. Anti-diarrheal treatment (loperamide or diphenoxylate hydrochloride) should be initiated promptly for diarrhea (1).

Vizimpro also has a warning for dermatologic adverse reactions, such as rash and exfoliative skin reactions. Vizimpro should be withheld for persistent Grade 2 of any Grade 3 or 4 dermatologic adverse reactions until recovery to less than or equal to Grade 1 severity, then Vizimpro can be resumed at the same or a reduced dose. The incidence and severity of rash and exfoliative skin reactions may increase with sun exposure. During Vizimpro initiation, moisturizers and appropriate sun limiting measures should be used (1).

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

Related policies
Erlotinib, Exkivity, Gilotrif, Iressa, Tagrisso

Policy

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

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

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

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Metastatic non-small cell lung cancer (NSCLC)

AND ALL of the following:

1. Tumor must have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as detected by an FDA-approved test
2. Prescriber agrees to monitor for serious adverse reactions including interstitial lung disease (ILD)/pneumonitis, diarrhea, and dermatologic reactions

Prior – Approval *Renewal* Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Metastatic non-small cell lung cancer (NSCLC)

AND ALL of the following:

1. **NO** disease progression or unacceptable toxicity
2. Prescriber agrees to monitor for serious adverse reactions including interstitial lung disease (ILD)/pneumonitis, diarrhea, and dermatologic reactions

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 90 tablets per 90 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Vizimpro (dacomitinib) is an irreversible inhibitor of the kinase activity of the human EGFR family (EGFR/HER1, HER2, and HER4) and certain EGFR activating mutations (exon 19 deletion or the exon 21 L858R substitution mutation). Vizimpro showed dose-dependent inhibition of EGFR and HER2 autophosphorylation and tumor growth in mice bearing subcutaneously implanted human tumor xenografts driven by HER family targets including mutated EGFR. Vizimpro also exhibited antitumor activity in orally-dosed mice bearing intracranial human tumor xenografts driven by EGFR amplifications. The safety and effectiveness of Vizimpro in pediatric patients have not been established (1).

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

References

1. Vizimpro [package insert]. NY, NY: Pfizer, Inc.; December 2020.
2. NCCN Drugs & Biologics Compendium® Dacomitinib 2023. National Comprehensive Cancer Network, Inc. Accessed on October 19, 2023.

Policy History

Date	Action
October 2018	Addition to PA
November 2018	Annual review
March 2019	Annual review
June 2020	Annual review
December 2021	Annual review and reference update
March 2022	Annual review and reference update
December 2023	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 8, 2023 and is effective on January 1, 2024.