



**VIZIMPRO  
(dacomitinib)**

**RATIONALE FOR INCLUSION IN PA PROGRAM**

**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 or 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).



**BlueCross  
BlueShield.**

Federal Employee Program.

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

### **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 2025. National Comprehensive Cancer Network, Inc. Accessed on January 14, 2025.