## SPECIALTY GUIDELINE MANAGEMENT

# **VIZIMPRO** (dacomitinib)

#### **POLICY**

#### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

## A. FDA-Approved Indication

Vizimpro is 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.

## B. Compendial Uses

NSCLC, recurrent, advanced or metastatic sensitizing EGFR mutation-positive

All other indications are considered experimental/investigational and not medically necessary.

### **II. DOCUMENTATION**

Submission of the following information is necessary to initiate the prior authorization review: For NSCLC, EGFR mutation testing results.

#### III. CRITERIA FOR INITIAL APPROVAL

### Non-small cell lung cancer (NSCLC)

Authorization of 12 months may be granted for treatment of recurrent, advanced or metastatic NSCLC when the member has sensitizing EGFR mutation-positive disease as a single agent.

### IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for EGFR positive NSCLC when either of the following criteria are met:

- 1. There is no evidence of unacceptable toxicity or disease progression while on the current regimen.
- 2. Disease is T790M negative and there is no evidence of unacceptable toxicity.

### V. REFERENCES

- 1. Vizimpro [package insert]. New York, NY: Pfizer Inc.; December 2020.
- 2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 4, 2024.

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Reference number(s)
2770-A

3. Wu YL, Cheng Y, Zhou X, et al. Dacomitinib versus gefitinib as first-line treatment for patients with *EGFR*-mutation-positive non-small-cell lung cancer (ARCHER 1050): a randomised, open-label, phase 3 trial. *Lancet Oncology*. 2017; 18:1454-66.

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