Reference number(s)
2770-A

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.

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.