CVS Caremark®

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| Reference number(s) |
| 2770-A |

# Specialty Guideline Management Vizimpro

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Vizimpro | dacomitinib |

## 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.

### FDA-approved Indication1

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.

### Compendial Use2-3

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

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

## Documentation

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

## Coverage Criteria

### Non-small cell lung cancer (NSCLC)1,2,3

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

## 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:

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

## References

1. Vizimpro [package insert]. New York, NY: Pfizer Inc.; December 2020.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 3, 2025.
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.