Clinical Policy: Dacomitinib (Vizimpro)

Reference Number: PA.CP.PHAR.399
Effective Date: 01.19
Last Review Date: 01.19

Revision Log

Description
Dacomitinib (Vizimpro®) is a second-generation, irreversible epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor.

FDA Approved Indication(s)
Vizimpro is indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) with EGFR exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health & Wellness® that Vizimpro is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Non-Small Cell Lung Cancer (must meet all)**:**

1. Diagnosis of NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Disease is recurrent or metastatic;
4. Disease is positive for an EGFR mutation (exon 19 deletion or exon 21 [L858R] substitution) as detected by an FDA-approved test;
5. Request meets one of the following (a or b):
   a. Dose does not exceed 45 mg (1 tablet) per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

II. Continued Therapy

A. Non-Small Cell Lung Cancer (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):

c. New dose does not exceed 45 mg (1 tablet) per day;
d. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
EGFR: epidermal growth factor receptor
FDA: Food and Drug Administration
NSCLC: non-small cell lung cancer

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
NSCLC	45 mg PO QD	45 mg/day

VI. Product Availability

Tablets: 15 mg, 30 mg, 45 mg

VII. References

1. Vizimpro Prescribing Information. New York, New York: Pfizer Inc.; September 2018. Available at: https://www.vizimpro.com/. Accessed September 28, 2018.
2. 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 randomized, open-label, phase 3 trial. Lancet Oncol 2017;18:1454-66. http://dx.doi.org/10.1016/S1470-2045(17)30608-3.

3. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer Version 6.2018. Available at https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed September 28, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	01.19	