

<b>Clinical Policy Title:</b>	dacomitinib
<b>Policy Number:</b>	RxA.557
<b>Drug(s) Applied:</b>	Vizimpro®
<b>Original Policy Date:</b>	03/06/2020
<b>Last Review Date:</b>	10/19/2023
<b>Line of Business Policy Applies to:</b>	All lines of business (except Medicare)

## Criteria

### 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. Age ≥ 18 years;
4. Disease is recurrent, advanced or metastatic;
5. Disease is positive for EGFR mutation (e.g., exon 19 deletion or L858R);
6. Request meets one of the following (a or b):\*
  - a. Dose does not exceed 45 mg per day;
  - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

\*Prescribed regimen must be FDA-approved or recommended by NCCN

#### Approval Duration

**Commercial:** 6 months

**Medicaid:** 6 months

### II. Continued Therapy Approval

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

1. Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):\*
  - a. New dose does not exceed 45 mg per day;
  - b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

\*Prescribed regimen must be FDA-approved or recommended by NCCN

#### Approval Duration

**Commercial:** 12 months

**Medicaid:** 12 months

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

**References**

1. 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. Available at: [http://dx.doi.org/10.1016/S1470-2045\(17\)30608-3](http://dx.doi.org/10.1016/S1470-2045(17)30608-3). Accessed July 25, 2022.
2. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer Version 6.2021. Available at [https://www.nccn.org/professionals/physician\\_gls/pdf/nscl.pdf](https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf) . Accessed July 26, 2022.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Clinical policy title updated 2. Line of business policy applies to was updated to All lines of business 3. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 4. Reference reviewed and updated.	09/22/2020	12/07/2020
Policy was reviewed: 1. Continued Therapy Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 2. References were reviewed and updated.	10/03/2021	12/07/2021
Policy was reviewed: 1. References were reviewed and updated.	07/26/2022	10/19/2022
Policy was reviewed.	10/19/2023	10/19/2023

