RXADVANCE
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Clinical Policy Title:	dacomitinib
Policy Number:	RxA.557
Drug(s) Applied:	Vizimpro®
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All lines of business

Background

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

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
dacomitinib (Vizimpro®)	NSCLC	45 mg PO once daily	45 mg/day

Dosage Forms

- Tablets: 15 mg, 30 mg, 45 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval 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 a sensitizing EGFR mutation (e.g., exon 19 deletion or insertion; exon 21 point mutation - L858R, L861Q; exon 18 point mutation - G719X; exon 20 point mutation - S768I);
6. 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*).

**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. 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 (1 tablet) 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

III. Appendices

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

- Contraindication(s):
  - None reported

- Boxed Warning(s):
  - None reported

APPENDIX D: General Information

- Permanently discontinue Vizimpro® if Interstitial Lung Disease (ILD) is confirmed.

References

1. Vizimpro® Prescribing Information. New York, New York: Pfizer Inc.; September 2018. Available at: https://www.vizimpro.com/. Accessed September 22, 2020.
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 8.2020. Available at https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf . Accessed September 22, 2020.
4. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at nccn.org. Accessed September 22, 2020.

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. Appendix D added general information. 5. Reference reviewed and updated.	09/22/2020	12/07/2020