UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1262-7
Program	Prior Authorization/Notification
Medication	Vizimpro® (dacomitinib)
P&T Approval Date	11/2018, 11/2019, 11/2020, 11/2021, 11/2022, 11/2023, 11/2024
Effective Date	2/1/2025

1. Background:

Vizimpro® (dacomitinib) is a kinase inhibitor 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. The National Cancer Comprehensive Network (NCCN) also recommends the use of Vizimpro as first-line or continuation of therapy for recurrent, advanced, or metastatic NSCLC with EGFR S768I, L861Q, and/or G719X mutation positive tumors.

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. <u>Patients less than 19 years of age</u>

1. **Vizimpro** will be approved based on the following criterion:

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. <u>Non-small cell lung cancer (NSCLC)</u>

1. **<u>Initial Authorization</u>**

   a. **Vizimpro** will be approved based on **<u>all</u>** of the following criteria:

      (1) Diagnosis of NSCLC

      -AND-

      (2) Disease is recurrent, advanced or metastatic

      -AND-

(3) Disease is positive for **one** of the following EGFR mutations:

(a) Exon 19 deletion
(b) Exon 21 L858R substitution
(c) S768I
(d) L861Q
(e) G719X

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Vizimpro** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Vizimpro therapy

Authorization will be issued for 12 months.

C. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Vizimpro [package insert]. Pfizer Labs: New York, NY; December 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org. Accessed September 25, 2024.

Program	Prior Authorization/Notification – Vizimpro (dacomitinib)
Change Control	
11/2018	New program.
11/2019	Annual review. Added NCCN recommended regimens criteria. Updated references.
11/2020	Annual review. Updated coverage criteria based on NCCN recommendations. Updated background and references.
11/2021	Annual review. Updated coverage criteria based on NCCN recommendations. Updated background and references.
11/2022	Annual review. Added coverage for EGFR S768I, L861Q, and G719X mutation positive tumors under coverage criteria for non-small cell lung cancer per NCCN guidelines. Updated background, added state mandate, and updated references.
11/2023	Annual review. Updated reference.
11/2024	Annual review. No changes to coverage criteria.