# PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology – Vizimpro Prior Authorization Policy
- Vizimpro® (dacomitinib tablets – Pfizer)

**REVIEW DATE:** 11/29/2023

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***INSTRUCTIONS FOR USE***

*THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.*

## CIGNA NATIONAL FORMULARY COVERAGE:

## OVERVIEW

Vizimpro, a tyrosine kinase inhibitor, 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.[1]

## Guidelines

National Comprehensive Cancer Network (NCCN) guidelines for NSCLC (version 5.2023 – November 8, 2023) recommend testing for sensitizing *EGFR* mutations in patients with metastatic disease.[2] Patients with sensitizing *EGFR* mutations have a significantly better response to the *EGFR* tyrosine kinase inhibitors (TKIs) [erlotinib, Gilotrif®, Iressa®, Tagrisso®, and Vizimpro]. The most common *EGFR* mutations are exon 19 deletions and exon 21 (L858R) substitution mutations. Other less common mutations that are also sensitive to *EGFR* TKIs include L861Q, G719X, and S768I; these mutations cumulatively account for approximately 10% of all *EGFR* mutations. NCCN recommends the *EGFR* TKIs as first-line treatment for patients with advanced or metastatic NSCLC with *EGFR* exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X, and S768I.

## POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Vizimpro. All approvals are provided for the duration noted below.

- **Vizimpro® (dacomitinib tablets ( Pfizer) is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):**

**FDA-Approved Indication**

1. **Non-Small Cell Lung Cancer.** Approve for 1 year if the patient meets the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has advanced or metastatic disease; AND
   - **C)** Patient has sensitizing *EGFR* mutation-positive non-small cell lung cancer as detected by an approved test.
     Note: Examples of sensitizing *EGFR* mutation-positive non-small cell lung cancer include the following: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X, and S768I.

**CONDITIONS NOT COVERED**

- **Vizimpro® (dacomitinib tablets ( Pfizer) is(are) considered experimental, investigational, or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):**

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

**REFERENCES**


1. Vizimpro® tablets [prescribing information]. New York, NY: Pfizer; December 2020.
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 5.2023 – November 8, 2023) © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 27, 2023.
3. The NCCN Drugs & Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 27, 2023. Search term: dacomitinib.


**HISTORY**

| Type of Revision | Summary of Changes | Review Date |
|---|---|---|
| Annual Revision | No criteria changes | 11/30/2022 |
| Annual Revision | No criteria changes | 11/29/2023 |


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