

DRUG POLICY

Bizengri® (zenocutuzumab-zbco)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Adults with advanced unresectable or metastatic non-small cell lung cancer (NSCLC) harboring a neuregulin 1 (NRG1) gene fusion with disease progression on or after prior systemic therapy.
2. Adults with advanced unresectable or metastatic pancreatic adenocarcinoma harboring a NRG1 gene fusion with disease progression on or after prior systemic therapy.

Compendial Uses

1. Recurrent NSCLC
2. Recurrent Pancreatic Adenocarcinoma
3. Biliary Tract Cancers

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Required Documentation

Submission of the following information is necessary to initiate the prior authorization review: neuregulin 1 (NRG1) gene fusion status.

Criteria for Initial Approval

Non-Small Cell Lung Cancer (NSCLC)

Authorization of 12 months may be granted for treatment of advanced unresectable, metastatic, or recurrent NSCLC when all of the following criteria are met:

1. Member has experienced disease progression on or after prior systemic therapy
2. Member has neuregulin 1 (NRG1) gene fusion positive disease.
3. The requested medication will be used as a single agent.

Pancreatic Adenocarcinoma

Authorization of 12 months may be granted for treatment of advanced unresectable, metastatic, or recurrent pancreatic adenocarcinoma when all of the following criteria are met:

1. Member has experienced disease progression on or after prior systemic therapy
2. Member has neuregulin 1 (NRG1) gene fusion positive disease.
3. The requested medication will be used as a single agent

Biliary Tract Cancer

Authorization of 12 months may be granted for treatment of unresectable, gross residual (R2), or metastatic biliary tract cancer (including intrahepatic and extrahepatic cholangiocarcinoma) when all of the following criteria are met:

1. Member has experienced disease progression on or after prior systemic therapy.
2. Member has neuregulin 1 (NRG1) gene fusion positive disease.
3. The requested medication will be used as a single agent.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the Criteria for Initial Approval section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Other

Bizengri (zenocutuzumab-zbco) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J9382 – Injection, zenocutuzumab-zbco, 1 mg (effective 7/1/25)
- J9999 – Not otherwise classified, antineoplastic drugs
- J3490 – unclassified drugs
- J3590 – unclassified biologics

REFERENCES

Bizengri [package insert]. Cambridge, MA: Merus US, Inc.; March 2025.

The NCCN Drugs & Biologics Compendium® © 2026 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed March 24, 2026.

Kim DW, Goto K, Schram A, et al. Durable efficacy of zenocutuzumab, a HER2 x HER3 bispecific antibody, in advanced NRG1 fusion-positive (NRG1+) non-small cell lung cancer (NSCLC) [abstract]. From the European Society for Medical Oncology (ESMO) Annals of Oncology; Volume 34, supplement 4: S1702-S1703; November 2023.

Kim DW, Schram AM, Hollebecque A, et al. The phase I/II eNRGy trial: zenocutuzumab in patients with cancers harboring *NRG1* gene fusions. *Future Oncol*. 2024;20(16):1057-1067. doi:10.2217/fon-2023-0824

National Comprehensive Cancer Network (NCCN). Referenced from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Non-Small Cell Lung Cancer V.3.2025. © National Comprehensive Cancer Network, Inc 2025.

POLICY HISTORY

Policy #: 05.05.80

Original Effective Date: May 29, 2025

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