Applicable Drugs: Bizengri (zenocutuzumab-zbco)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 8/31/2026

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I to IV are met.)

I. Documentation of one of the following FDA-approved diagnoses A through C AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication(s)

A. Non-small cell lung cancer

i. Advanced, unresectable, or metastatic disease

ii. Documented neuregulin 1 (NRG1) gene fusion

iii. Documented disease progression on or after at least 1 prior systemic therapy

B. Pancreatic adenocarcinoma

i. Advanced, unresectable, or metastatic disease

ii. Documented neuregulin 1 (NRG1) gene fusion

iii. Documented disease progression on or after at least 1 prior systemic therapy

C. Cholangiocarcinoma

i. Advanced, unresectable, or metastatic disease

ii. Documented neuregulin 1 (NRG1) gene fusion

iii. Documented disease progression on or after at least 1 prior systemic therapy

II. Treatment must be prescribed by or in consultation with an oncologist or hematologist.

III. Request is for a medication with the appropriate FDA labeling, or its use is supported by current National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A.

IV. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- N/A

Other Criteria

- N/A

Quantity / Days Supply Restrictions

- Quantity is limited to 4 vials (375 mg each) for a 28-day supply

Approval Length

- **Authorization:** 6 months
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

Appendix

N/A

References

1. Bizengri. Prescribing Information. Merus BV. 2026. Accessed June 18, 2026. www.bizengri.com/pdf/pi/pdf
2. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Non-Small Cell Lung Cancer. Version 6.2026. Updated June 12, 2026. Accessed June 18, 2026.
3. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Pancreatic Adenocarcinoma. Version 2.2026. Updated April 22, 2026. Accessed June 18, 2026.
4. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Biliary Tract Cancers. Version 1.2026. Updated March 10, 2026. Accessed June 18, 2026.
5. Schram AM, Goto K, Kim DW, et al. Efficacy of zenocutuzumab in NRG1 fusion-positive cancer. N Engl J Med. 2025 Feb 6;392(6):566-576. doi: 10.1056/NEJMoa2405008
6. 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