Reference number(s)
6756-A

Standard Medicare Part B Management Bizengri

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Bizengri	zenocutuzumab-zbco

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit 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.
- Adults with advanced unresectable or metastatic pancreatic adenocarcinoma harboring a NRG1 gene fusion with disease progression on or after prior systemic therapy.

Compendial Uses[2]

- Recurrent NSCLC
- Recurrent Pancreatic Adnenocarcinoma

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this policy should be accompanied by supporting evidence from Medicare approved compendia.

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Documentation

Submission of the following information must be available, upon request for initial approval: NRG1 gene fusion status.

Coverage Criteria

Non-Small Cell Lung Cancer (NSCLC)[1,2]

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

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

Pancreatic Adenocarcinoma[1,2]

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:

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

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.
- The requested medication is being used to treat an indication listed in coverage criteria section.
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen, AND
    - No evidence of disease progression while on the current regimen.

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Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Bizengri.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: Non-small cell lung cancer
- NCCN Guideline: Pancreatic adenocarcinoma

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Bizengri are covered in addition to the following:

- Recurrent NSCLC
- Recurrent Pancreatic Adenocarcinoma

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Bizengri to treat recurrent NSCLC and recurrent pancreatic adenocarcinoma can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

References

1. Bizengri [package insert]. Lexington, MA: Partner Therapeutics, Inc.; March 2025.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed December 5, 2025.

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