Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Bizengri (zenocutuzumab-zbco)	MP-RX-FP-165-25	☒ MMM MA ☒ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B Drugs
☐ Other _____

Service Description

This document addresses the use of Bizengri (zenocutuzumab-zbco) injection , a drug approved by the Food and Drug Administration (FDA) for the treatment of non-small cell lung cancer (NSCLC) and pancreatic adenocarcinoma.

Background Information

The FDA approved indications for Bizengri include 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. Bizengri is also indicated for adults with advanced, unresectable or metastatic pancreatic adenocarcinoma harboring a neuregulin 1 (NRG1) gene fusion with disease progression on or after prior systemic therapy. These indications are approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Bizengri has a black box warning regarding embryo-fetal toxicity. It is recommended to advise patients of this risk and the need for effective contraception.

Definitions and Measures

Adenocarcinoma: Cancer originating in cells that line specific internal organs and that have gland-like (secretory) properties.

Disease Progression: Cancer that continues to grow or spread.

Metastasis: The spread of cancer from one part of the body to another; a metastatic tumor contains cells that are like those in the original (primary) tumor and have spread.

Non-small cell lung cancer: A group of lung cancers that are named for the kinds of cells found in the cancer and how the cells look under a microscope. The three main types of non-small cell lung cancer are squamous cell carcinoma, large cell carcinoma, and adenocarcinoma.

Unresectable: Unable to be removed with surgery.

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Approved Indications

A. 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

B. Adults with advanced, unresectable or metastatic pancreatic adenocarcinoma harboring a neuregulin 1 (NRG1) gene fusion with disease progression on or after prior systemic therapy.

Other Uses

A. N/A

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Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS	Description
J9382	Injection, zenocutuzumab-zbco, 1 mg

ICD-10	Description
	All diagnosis pend

Medical Necessity Guidelines

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Bizengri (zenocutuzumab-zbco)

A. Criteria For Initial Approval

i. Individual has a diagnosis of advanced, unresectable or metastatic non-small cell lung cancer (NSCLC); **AND**
ii. Individual has neuregulin 1 (NRG1) gene fusion; **AND**
iii. Individual has disease progression on or after prior systemic therapy;

OR

iv. Individual has a diagnosis of advanced, unresectable or metastatic pancreatic adenocarcinoma; **AND**
v. Individual has neuregulin 1 (NRG1) gene fusion; **AND**
vi. Individual has disease progression on or after prior systemic therapy.

B. Criteria For Continuation of Therapy

i. MMM considers continuation of Bizengri (zenocutuzumab-zbco) therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) when there is no evidence of unacceptable toxicity or disease progression, or the maximum duration of therapy has not been exceeded. The following information should be supplied for reauthorization:
    a. A current oncology note documenting the patient's response to treatment showing no progression of disease.
    b. Current imaging studies and other objective measures, as appropriate, showing no progression of disease when compared with previous results.

C. Authorization Duration

i. Initial Approval Duration: 6 months
ii. Reauthorization Approval Duration: Up to 6 months

D. **Conditions Not Covered**
Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

i. Bizengri (zenocutuzumab-zbco) may not be approved when the above criteria are not met and for all other indications.

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Limits or Restrictions

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Drug	Limit
Bizengri ((zenocutuzumab-zbco) 375 mg/18.75 mL	4 vials per 28 days
Exceptions	
N/A	

Reference Information

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: March 4, 2025
2. *2025 ICD-10-CM codes C25*: Malignant neoplasm of pancreas* (no date) *ICD10data.com*. Available at: https://www.icd10data.com/ICD10CM/Codes/C00-D49/C15-C26/C25- (Accessed: 04 March 2025).

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Policy History

Revision Type	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Select Review 1/7/2026	Coding reviewed: J9382 added for Bizengri.	N/A	N/A
Policy Inception 3/11/2025	Elevance Health's Medical Policy adoption	N/A	4/2/2025