

Medical Drug Clinical Criteria

Subject: Bizengri (zenocutuzumab-zbco)

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Overview

This document addresses the use of Bizengri (zenocutuzumab-zbco) injection. Bizengri is a bispecific HER2- and HER3-directed antibody primarily used to treat non-small cell lung cancer (NSCLC) and pancreatic adenocarcinoma.

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.

Clinical Criteria

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.

Bizengri (zenocutuzumab-zbco)

Requests for Bizengri (zenocutuzumab-zbco) may be approved if the following criteria are met:

- 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.

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

Quantity Limits

Quantity Limits

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

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

C9399	Unclassified drugs or biologicals [Bizengri (zenocutuzumab-zbco)]
J9999	Not otherwise classified, antineoplastic drugs [Bizengri (zenocutuzumab-zbco)]

ICD-10 Diagnosis

All diagnosis pend

Document History

New: 12/09/2024

Document History:

- 12/09/2024 – Select Review: Add clinical criteria and quantity limits for Bizengri. Coding reviewed: Added HCPCS NOC C9399, J9999, and all diagnosis pend for Bizengri.

References

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: December 5, 2024
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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