

PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Bizengri Prior Authorization Policy

- Bizengri® (zenocutuzumab-zbco intravenous infusion –Merus/Partner)

REVIEW DATE: 12/18/2024

OVERVIEW

Bizengri, a bispecific human epidermal growth factor receptor 2 and 3 (HER2)- and (HER3)-directed antibody, is indicated for the treatment of:¹

- Non-small cell lung cancer (NSCLC), advanced, unresectable or metastatic, harboring a neuregulin 1 (*NRG1*) gene fusion with disease progression on or after prior systemic therapy in adults.
- Pancreatic adenocarcinoma, advanced, unresectable or metastatic, harboring a *NRG1* gene fusion with disease progression on or after prior systemic therapy in adults.

Guidelines

Bizengri is not discussed in guidelines from the National Comprehensive Cancer Network (NCCN):

- **NSCLC:** NCCN guidelines (version 1.2025 – December 20, 2024) recommend molecular testing for patients with advanced or metastatic disease.² Recommendations are given based on the type of mutation or gene fusion. Generally, platinum based therapy such as carboplatin and cisplatin are used and programmed cell death protein 1 (PD)-1 or PD-ligand 1 (PD-L1) blockers are used as systemic therapy. Bizengri is recommended as a subsequent therapy for patients with the *NRG1* gene fusion for patients with recurrent, advanced, or metastatic disease (category 2A).
- **Pancreatic Adenocarcinoma:** NCCN guidelines (version 1.2025 – December 20, 2024) recommend tumor/somatic molecular profiling for patients with locally advanced/metastatic disease who are candidates for anti-cancer therapy to identify uncommon mutations, such as *NRG1* fusions.³ Bizengri is not included in these guidelines. For patient with advanced or metastatic disease, clinical trial is preferred. For patients with metastatic or advanced disease, some of the “Preferred” regimens include FOLFIRINOX (fluorouracil + leucovorin + irinotecan + oxaliplatin) or a modified FOLFIRINOX with or without subsequent chemoradiation; and gemcitabine + albumin-bound paclitaxel with or without subsequent chemoradiation. There are other recommendations based on performance status and mutation type. There are no recommendations for patients with *NRG1* fusions.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Bizengri. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Bizengri, as well as the monitoring required for adverse events and long-term efficacy, approval requires Bizengri to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Bizengri is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Non-Small Cell Lung Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D and E):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has advanced, unresectable, or metastatic disease; AND
 - C) The disease is neuregulin 1 (*NRG1*) gene fusion positive; AND
 - D) Patient has tried at least one systemic regimen; AND

Note: Examples of a systemic regimen include one or more of the following drugs: carboplatin, cisplatin, or programmed cell death protein 1 (PD)-1 or PD-ligand 1 (PD-L1) blockers.

 - E) The medication will be prescribed by or in consultation with an oncologist.
2. **Pancreatic Adenocarcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D and E):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has advanced, unresectable, or metastatic disease; AND
 - C) The disease is neuregulin 1 (*NRG1*) gene fusion positive; AND
 - D) Patient has tried at least one systemic regimen; AND

Note: Examples of systemic regimen include one or more of the following drugs: fluorouracil, leucovorin, irinotecan, oxaliplatin, gemcitabine, paclitaxel, capecitabine

- E) The medication will be prescribed by or in consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Bizengri is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Bizengri® intravenous infusion [prescribing information]. Cambridge, MA: Merus; December 2024.
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 1.2025 – December 20, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on December 30, 2024.
3. The NCCN Pancreatic Adenocarcinoma Cancer Clinical Practice Guidelines in Oncology (version 1.2025 – December 20, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on December 30, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	12/18/2024
Update	Updated the overview section to include updated NCCN guidelines.	12/30/2024