

# Specialty Guideline 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

- 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.

All other indications are considered experimental/investigational and not medically necessary.

### Documentation

Submission of the following information is necessary to initiate the prior authorization review: neuregulin 1 (NRG1) gene fusion status.

## Coverage Criteria

### Non-Small Cell Lung Cancer (NSCLC)

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

- Member has experienced disease progression on or after prior systemic therapy AND
- Member has neuregulin 1 (NRG1) gene fusion positive disease.

### Pancreatic Adenocarcinoma

Authorization of 12 months may be granted for treatment of advanced unresectable or metastatic pancreatic adenocarcinoma when both of the following criteria are met:

- Member has experienced disease progression on or after prior systemic therapy AND
- Member has neuregulin 1 (NRG1) gene fusion positive disease.

## Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the Coverage Criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

## References

1. Bizengri [package insert]. Cambridge, MA: Merus US, Inc.; December 2024.