



**Bizengri**  
**Bizengri (zenocutuzumab-zbco) J9382**  
**Prior Authorization Request**  
**Medicare Part B Form**

Instructions: \* Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.

<input type="checkbox"/>	<b>Standard Request– (72 Hours)</b>	<input type="checkbox"/>	<b>Urgent Request</b> (standard time frame could place the member's life, health or ability in serious jeopardy)
Date Requested _____			
Requestor _____ Clinic name: _____ Phone _____ / Fax _____			

**MEMBER INFORMATION**

\*Name: \_\_\_\_\_ \*ID#: \_\_\_\_\_ \*DOB: \_\_\_\_\_

**PRESCRIBER INFORMATION**

\*Name: \_\_\_\_\_  MD  FNP  DO  NP  PA \*Phone: \_\_\_\_\_

\*Address: \_\_\_\_\_ \*Fax: \_\_\_\_\_

**DISPENSING PROVIDER / ADMINISTRATION INFORMATION**

\*Name: \_\_\_\_\_ Phone: \_\_\_\_\_

\*Address: \_\_\_\_\_ Fax: \_\_\_\_\_

**PROCEDURE / PRODUCT INFORMATION**

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht: _____ )	Frequency	End Date if known

Self-administered       Provider-administered       Home Infusion

Chart notes attached. **Other important information:** \_\_\_\_\_

**Diagnosis: ICD10:** \_\_\_\_\_ **Description:** \_\_\_\_\_

Provider attests the diagnosis provided is an FDA-Approved indication for this drug

**CLINICAL INFORMATION**

**New Start or Initial Request: (Clinical documentation required for all requests)**

**Advanced, recurrent, unresectable or metastatic non-small cell lung cancer (NSCLC)**

Patient has neuregulin 1 (NRG1) gene fusion; AND

Patient has disease progression on or after prior systemic therapy;

**Advanced, recurrent, unresectable or metastatic pancreatic adenocarcinoma**

Patient has neuregulin 1 (NRG1) gene fusion; AND

Patient has disease progression on or after prior systemic therapy.

If not, please provide **clinical rationale** for formulary exception: \_\_\_\_\_

\_\_\_\_\_

Continuation Requests: (Clinical documentation required for all requests)

Patient had an **adequate response** or **significant improvement** while on this medication.

Medical record documentation of positive response is included

If not, please provide clinical rationale for continuing this medication: \_\_\_\_\_

\_\_\_\_\_

#### ACKNOWLEDGEMENT

**Request By (Signature Required):** \_\_\_\_\_ **Date:** \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

## Prior Authorization Group – Bizengri Prior Authorization

### Drug Name(s):

**BIZENGRİ**

**ZENOCUTUZUMAB-ZBCO**

### Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Prescribed by, or in consultation with an oncologist or other cancer specialist related to the diagnosis.
3. Drug is being used appropriately per NCCN, CMS recognized compendia, authoritative medical literature, evidence based guidelines and/or accepted standards of medical practice.
4. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.
  - If the member meets all these criteria, they may be approved by the Plan for the requested drug.
  - Quantity limits and tiering will be determined by the Plan, in accordance with the Label.

### Exclusion Criteria:

**N/A**

### Prescriber Restrictions:

**Oncologist or other related specialist**

### Coverage Duration:

**Approval will be for 6 months**

### FDA Indications:

**Bizengri**

- Non-small cell lung cancer, Advanced unresectable or metastatic, NRG1 Fusion-positive, with disease progression on or after prior systemic therapyView additional information.
- Pancreatic cancer, Adenocarcinoma, advanced unresectable or metastatic, NRG1 Fusion-positive, with disease progression on or after prior systemic therapy

### Off-Label Uses:

**N/A**

### Age Restrictions:

Safety and efficacy not established in pediatric patients.

### Other Clinical Consideration:

#### **Intravenous (Solution)**

- Exposure to zenocutuzumab-zbco during pregnancy can cause embryo-fetal harm. Advise patients of this risk and the need for effective contraception

### Resources:

[https://www.micromedexsolutions.com/micromedex2/librarian/CS/CDC9A8/ND\\_PR/evidencexpert/ND\\_P/evidencexpert/DUPLICATIONSHIELDSYNC/09D333/ND\\_PG/evidencexpert/ND\\_B/evidencexpert/ND\\_AppProduct/evidencexpert/ND\\_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=934583&contentSetId=100&title=Zenocutuzumab-zbco&servicesTitle=Zenocutuzumab-zbco&brandName=Bizengri&UserMdxSearchTerm=Bizengri#](https://www.micromedexsolutions.com/micromedex2/librarian/CS/CDC9A8/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/09D333/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=934583&contentSetId=100&title=Zenocutuzumab-zbco&servicesTitle=Zenocutuzumab-zbco&brandName=Bizengri&UserMdxSearchTerm=Bizengri#)