BIZENGRI® BILLING AND CODING GUIDE

This guide provides an overview of coding information related to filing claims for BIZENGRI. Please note that the use of the following codes does not guarantee payment or coverage for any product or service.

Bizengri®
zenocutuzumab-zbco
20 mg/mL Injection for IV Use

National Drug Code (NDC)[1]

Administration Method	Dose	Code
Intravenous infusion by HCP	Carton contains 2 single-use vials each containing 375 mg/18.75 mL (20 mg/mL) of BIZENGRI	10-digit NDC: 71837-1000-2 11-digit NDC: 71837-1000-02

Although the FDA uses a 10-digit format when registering NDC numbers, payers often require an 11-digit NDC format on claim forms for billing purposes. It is important to confirm with your payer which NDC format is required. In addition, Medicaid requires that all claims for provider-administered drugs include NDC numbers.

This reporting requirement may also be implemented by some commercial payers. Guidelines for reporting the NDC number in the appropriate format, quantity, and unit of measure vary by state and by payer and should be reviewed prior to submitting a claim.

Healthcare Common Procedure Coding System (HCPCS)

The HCPCS codes below are assigned by the CMS to describe the administration of BIZENGRI in the physician's office setting. The miscellaneous J-codes below may be used for BIZENGRI until the CMS assigns a permanent code.

Code	Description
J9999[2]	Not otherwise classified, antineoplastic drugs
J3590[3]	Unclassified biologics

Report name of drug, dosage, and route of administration in item 19 of the CMS-1500.

Current Procedural Terminology (CPT)[4]

CPT codes are used to describe how the product was administered.

Code	Description
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug.
96415	Chemotherapy administration, intravenous infusion technique; each additional hour. Report in conjunction with 96413. Report for infusion intervals of greater than 30 minutes beyond 1-hour increments.

HCPs should consult the payer or Medicare contractor to determine the code most appropriate to report for administration. It is the provider's responsibility to ensure that the codes used are consistent with payer policy and reflect the service performed.

CMS, Centers for Medicare & Medicaid Services; FDA, US Food and Drug Administration; HCP, healthcare professional.

The coding information in this guide is general in nature and subject to change without notice. Partner Therapeutics cannot guarantee insurance coverage or reimbursement. Coverage and reimbursement may vary significantly by payer, plan, patient, and patient status. It is the sole responsibility of the healthcare provider to select the appropriate codes and modifiers and to confirm payer policies on coverage, prior authorization, coding, and claims billing. This coding and billing guide is intended for informational purposes only.

Please see Indications and Important Safety Information, including BOXED WARNING, here.

Diagnosis Codes

Below is a list of a variety of *ICD-10-CM* codes for cancer in the lungs and pancreas that may be relevant for treatment with BIZENGRI.

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***ICD-10* coding for NSCLC[5]**	**Description[5]**
C34.0	Malignant neoplasm of main bronchus
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.1	Malignant neoplasm of upper lobe, bronchus or lung
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.3	Malignant neoplasm of lower lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.8	Malignant neoplasm of overlapping sites of bronchus and lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.9	Malignant neoplasm of unspecified part of bronchus or lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
***ICD-10* coding for pancreatic adenocarcinoma[6]**	**Description[6]**
C25.3	Malignant neoplasm of pancreatic duct

The *ICD-10-CM* diagnosis codes listed above are provided only as examples of potentially relevant codes. Providers should consult a current *ICD-10-CM* manual and always select the most appropriate diagnosis code(s) with the highest level of specificity to describe a patient's actual condition.

The information provided in this guide is of a general nature, for informational purposes only, and is not intended to be a comprehensive list nor instructive. Coding and coverage policies change periodically and often without warning. The responsibility to determine coverage and reimbursement parameters, and appropriate coding for a particular patient and/or procedure, is always the responsibility of the provider or physician. The information provided in this guide should in no way be considered a guarantee of coverage or reimbursement for any product or service.

For 340B Modifier: Beginning January 1, 2023, Medicare requires that all claims submitted by 340B-covered entities on OPPS claims (bill type 13X) for separately payable Part B drugs and biologics must include modifiers "JG" (Drug or biologic acquired with 340B drug pricing program discount, reported for informational purposes) or "TB" (Drug or biologic acquired with 340B drug pricing program discount, reported for informational purposes for select entities) on claim lines for drugs acquired through the 340B Drug Discount Program. Additional provider types will be required to use these modifiers in 2024.

ICD-10, International Classification of Disease, Tenth Revision; *ICD-10-CM, International Classification of Disease, Tenth Revision, Clinical Modification*; NSCLC, non–small cell lung cancer.

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Please see Indications and Important Safety Information, including BOXED WARNING, here.

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR BIZENGRI® (zenocutuzumab-zbco)

Bizengri®
zenocutuzumab-zbco
20 mg/mL Injection for IV Use

INDICATIONS

BIZENGRI is indicated for the treatment of 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 indicated for the treatment of 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 these indications may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

IMPORTANT SAFETY INFORMATION

BOXED WARNING: EMBRYO-FETAL TOXICITY

Embryo-Fetal Toxicity: Exposure to BIZENGRI during pregnancy can cause embryo-fetal harm. Advise patients of this risk and the need for effective contraception.

WARNINGS AND PRECAUTIONS

Infusion-Related Reactions/Hypersensitivity/Anaphylactic Reactions

BIZENGRI can cause serious and life-threatening infusion-related reactions (IRRs), hypersensitivity and anaphylactic reactions. Signs and symptoms of IRR may include chills, nausea, fever, and cough.

In the eNRGy study, 13% of patients experienced IRRs, all were Grade 1 or 2; 91% occurred during the first infusion.

Administer BIZENGRI in a setting with emergency resuscitation equipment and staff who are trained to monitor for IRRs and to administer emergency medications. Monitor patients closely for signs and symptoms of infusion reactions during infusion and for at least 1 hour following completion of first BIZENGRI infusion and as clinically indicated. Interrupt BIZENGRI infusion in patients with ≤ Grade 3 IRRs and administer symptomatic treatment as needed. Resume infusion at a reduced rate after resolution of symptoms. Immediately stop the infusion and permanently discontinue BIZENGRI for Grade 4 or life-threatening IRR or hypersensitivity/anaphylaxis reactions.

Interstitial Lung Disease/Pneumonitis

BIZENGRI can cause serious and life-threatening interstitial lung disease (ILD)/pneumonitis.

In the eNRGy study, ILD/pneumonitis occurred in 2 (1.1%) patients treated with BIZENGRI. Grade 2 ILD/pneumonitis (Grade 2) resulting in permanent discontinuation of BIZENGRI occurred in 1 (0.6%) patient.

Monitor for new or worsening pulmonary symptoms indicative of ILD/pneumonitis (e.g., dyspnea, cough, fever). Immediately withhold BIZENGRI in patients with suspected ILD/pneumonitis and administer corticosteroids as clinically indicated. Permanently discontinue BIZENGRI if ILD/pneumonitis ≥ Grade 2 is confirmed.

Left Ventricular Dysfunction

BIZENGRI can cause left ventricular dysfunction.

Left ventricular ejection fraction (LVEF) decrease has been observed with anti-HER2 therapies, including BIZENGRI. Treatment with BIZENGRI has not been studied in patients with a history of clinically significant cardiac disease or LVEF less than 50% prior to initiation of treatment.

In the eNRGy study, Grade 2 LVEF decrease (40%-50%; 10 - 19% drop from baseline) occurred in 2% of evaluable patients. Cardiac failure without LVEF decrease occurred in 1.7% of patients, including 1 (0.6%) fatal event.

Before initiating BIZENGRI, evaluate LVEF and monitor at regular intervals during treatment as clinically indicated. For LVEF of less than 45% or less than 50% with absolute decrease from baseline of 10% or greater is confirmed, or in patients with symptomatic congestive heart failure (CHF), permanently discontinue BIZENGRI.

Embryo-Fetal Toxicity

Based on its mechanism of action, BIZENGRI can cause fetal harm when administered to a pregnant woman. No animal reproduction studies were conducted with BIZENGRI. In postmarketing reports, use of a HER2-directed antibody during pregnancy resulted in cases of oligohydramnios manifesting as fatal pulmonary hypoplasia, skeletal abnormalities, and neonatal death. In animal models, studies have demonstrated that inhibition of HER2 and/or HER3 results in impaired embryo-fetal development, including effects on cardiac, vascular and neuronal development, and embryolethality.

Please see additional Important Safety Information on the next page.

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IMPORTANT SAFETY INFORMATION (cont.)

WARNINGS AND PRECAUTIONS (cont.)

Embryo-Fetal Toxicity (cont.)

Advise patients of the potential risk to a fetus. Verify the pregnancy status of females of reproductive potential prior to the initiation of BIZENGRI. Advise females of reproductive potential to use effective contraception during treatment with BIZENGRI and for 2 months after the last dose.

ADVERSE REACTIONS

***NRG1* Gene Fusion Positive Unresectable or Metastatic NSCLC**

Serious adverse reactions occurred in 25% of patients with *NRG1* gene fusion positive NSCLC who received BIZENGRI (n=99). Serious adverse reactions in ≥ 2% of patients included pneumonia (n=4), dyspnea and fatigue (n=2 each).

Fatal adverse reactions occurred in 3 (3%) patients and included respiratory failure (n=2), and cardiac failure (n=1).

Permanent discontinuation of BIZENGRI due to an adverse reaction occurred in 3% of patients. Adverse reactions resulting in permanent discontinuation of BIZENGRI included dyspnea, pneumonitis and sepsis (n=1 each).

In patients with *NRG1* gene fusion positive NSCLC who received BIZENGRI, the most common (>20%) adverse reactions, including laboratory abnormalities, were decreased hemoglobin (35%), increased alanine aminotransferase (30%), decreased magnesium (28%), increased alkaline phosphatase (27%), decreased phosphate (26%), diarrhea (25%), musculoskeletal pain (23%), increased gamma-glutamyl transpeptidase (23%), increased aspartate aminotransferase (22%) and decreased potassium (21%).

***NRG1* Gene Fusion Positive Unresectable or Metastatic Pancreatic Adenocarcinoma**

Serious adverse reactions occurred in 23% of patients with *NRG1* gene fusion positive pancreatic adenocarcinoma who received BIZENGRI (=39).

There were 2 fatal adverse reactions, one due to COVID-19 and one due to respiratory failure.

In patients with *NRG1* gene fusion positive pancreatic adenocarcinoma who received BIZENGRI the most common (≥20%) adverse reactions, including laboratory abnormalities, were increased alanine aminotransferase (51%), diarrhea (36%), increased aspartate aminotransferase (31%), increased bilirubin (31%), decreased phosphate (31%), increased alkaline phosphatase (28%), decreased sodium (28%), musculoskeletal pain (28%), decreased albumin (26%), decreased potassium (26%), decreased platelets (26%), decreased magnesium (24%), increased gamma-glutamyl transpeptidase (23%), decreased hemoglobin (23%), vomiting (23%), nausea (23%), decreased leukocytes (21%) and fatigue (21%).

Please click here for full Prescribing Information, Important Safety Information, including BOXED WARNING, and Patient Information.

References: 1. BIZENGRI. Prescribing information. Partner Therapeutics, Inc.; 2025. **2.** National Cancer Institute. Surveillance, Epidemiology, and End Results Program. CanMED: HCPCS. Accessed March 14, 2025. https://seer.cancer.gov/oncologytoolbox/canmed/hcpcs/1185/ **3.** Centers for Medicare and Medicaid Services. Billing and coding: hospital outpatient drugs and biologicals under the Outpatient Prospective Payment System (OPPS). Accessed August 8, 2024. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=55913 **4.** Centers for Medicare and Medicaid Services. Billing and coding: approved drugs and biologicals; includes cancer chemotherapeutic agents. Accessed August 8, 2024. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=53049&ver=98 **5.** ICD-10 Data. 2024 ICD-10-CM Codes: Malignant neoplasm of bronchus and lung C34. Accessed August 12, 2024. https://www.icd10data.com/ICD10CM/Codes/C00-D49/C30-C39/C34- **6.** ICD-10 Data. 2024 ICD-10-CM Codes: Malignant neoplasm of pancreas C25. Accessed August 12, 2024. https://www.icd10data.com/ICD10CM/Codes/C00-D49/C15-C26/C25-

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