BIZENGRI® *(zenocutuzumab-zbco)*

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<tr><th>PA Criteria</th><th>Criteria Details</th></tr>
<tr><td>Description</td><td>BIZENGRI® is a bispecific human epidermal growth factor 2 (HER2) and HER3-directed antibody.</td></tr>
<tr><td>Covered Uses
(FDA approved indication)</td><td>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*.
adults with advanced, unresectable or metastatic pancreatic adenocarcinoma harboring a neuregulin 1 (NRG1) gene fusion with disease progression on or after prior systemic therapy*.
*This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trial.</td></tr>
<tr><td>Dosing and Administration</td><td>
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<tr><th>Indication</th><th>Dosing Regimen</th></tr>
<tr><td>NSCLC, pancreatic adenocarcinoma</td><td>750 mg IV infusion every two weeks; administer infusion over four hours

Continue until disease progression or unacceptable toxicity.

Recommended Premedications prior to EACH infusion:
<table>
<tr><th>Premedication</th><th>Dose</th><th>Route of Administration</th></tr>
<tr><td>Corticosteroid*</td><td>Dexamethasone 10 mg</td><td>PO or IV</td></tr>
<tr><td>Antipyretic</td><td>APAP 1000 mg</td><td>PO or IV</td></tr>
<tr><td>H1 Antihistamine</td><td>Dexchlorpheniramine 5 mg or other anti-H1 equivalent</td><td>PO or IV</td></tr>
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*Optional after initial BIZENGRI infusion</td></tr>
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<tr><td>Billing and Coding Information</td><td>
<table>
<tr><th>10-digit NDC</th><th>11-digit NDC</th></tr>
<tr><td>71837-1000-2</td><td>71837-1000-02</td></tr>
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<table>
<tr><th>HCPCS Code</th><th>Description</th></tr>
<tr><td>J9382</td><td>Injection, zenocutuzumab-zbco, 1 mg</td></tr>
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<tr><th>CPT Procedural Codes</th><th>Description</th></tr>
<tr><td>96413</td><td>Chemotherapy IV infusion, up to one hour</td></tr>
<tr><td>96415</td><td>Chemotherapy IV infusion, additional hour*</td></tr>
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*Used as an add-on code for every hour of infusion that is more than 30 min past the initial 1 hour</td></tr>
<tr><td>Product Availability</td><td>Single dose vial: 375 mg/18.75 mL (two vials per carton = 750 mg = 37.5 mL)</td></tr>
<tr><td>Contraindications</td><td>None.</td></tr>
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Recommended Medical Monitoring	Patients received BIZENGRI® are chosen based on the presence of an NRG1 gene fusion in tumor specimens with disease progression. **BLACK BOX WARNING: Embryo-Fetal Toxicity** – BIZENGRI can cause fetal harm when administered to pregnant women, including effects on cardiac, vascular and neuronal development, and embryolethality. a. Advise patients of potential risk to fetus; verify pregnancy status of females of reproductive potential prior to initiation of therapy b. Recommend effective contraception during treatment and for two months after last dose. Patients should be monitored for any of these reactions. BIZENGRI dose may be delayed, reduced or permanently discontinued based on the severity of adverse reactions. BIZENGRI® has been associated with: a. Infusion-related reactions (IRR)/Hypersensitivity/Anaphylactic Reactions b. Interstitial Lung Disease (ILD) and Pneumonitis c. Left Ventricular Dysfunction d. Embryo-fetal Toxicity **(BBW)**
Approval Criteria **NSCLC**	a. Physician administered IV infusion; in-office or HOPD i. Cannot be self-administered b. Non-Small Cell Lung Cancer **(must meet all)**: i. Diagnosis of advanced, unresectable or metastatic NSCLC ii. Prescribed by or in consultation with an oncologist iii. Patient age ≥ 18 years iv. Disease is positive for NRG1 gene fusion v. Failure of at least one prior systemic therapy (see Appendix) vi. Request meets one of the following: 1. Dose does not exceed 750 mg every two weeks 2. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence)
Approval Criteria **Pancreatic Adenocarcinoma**	a. Physician administered IV infusion; in-office or HOPD i. Cannot be self-administered b. Pancreatic Adenocarcinoma (must meet all): i. Diagnosis of advanced, unresectable or metastatic pancreatic adenocarcinoma ii. Prescribed by or in consultation with an oncologist iii. Patient age ≥ 18 years iv. Disease is positive for NRG1 gene fusion v. Failure of at least one prior systemic therapy (see Appendix) vi. Request meets one of the following: 1. Dose does not exceed 750 mg every two weeks vii. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence)

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<tr><td>Age Restriction</td><td>Adults ≥ 18 years old.</td></tr>
<tr><td>Coverage Duration</td><td>Initial: six months. Reauthorization: 12 months.

Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.</td></tr>
<tr><td>Appendix</td><td>Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document.

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<tr><th>Examples of systemic therapies for NSCLC</th><th>Examples of systemic therapies for pancreatic adenocarcinoma</th></tr>
<tr><td>a. Platinum therapies (e.g. carboplatin, cisplatin)
b. Anti-PD1/PD-L1 therapy (e.g. Keytruda, Libtayo, Opdivo, Imfinzi, Tecentriq)
c. Bevacizumab (Avastin, Alymsys, Avzivi, Mvasi, Vegzelma, Zirabev)
d. Gemcitaine
e. Taxane chemotherapy (e.g. Paclitaxel, Docetaxel)</td><td>a. FOLFIRINOX (fluorouracil + leucovorin + irinotecan + oxaliplatin)
b. NALIRIFOX (liposomal irinotecan + fluorouracil + leucovorin + oxaliplatin)
c. Gemcitabine-based therapy
d. Capecitabine-based therapy
e. Taxane-based chemotherapy (e.g. albumin-bound paclitaxel)</td></tr>
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STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	9/9/2025	9/9/2025	Tamara Chinarian, PharmD, Clinical Pharmacist	N/A
Approved	N/A	11/13/2025	Pharmacy & Therapeutics (P&T) Committee	11/13/2025