Zenocutuzumab (BIZENGRI)
Criteria for Use
June 2025

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National Formulary Committee Monograph on this drug at the *PBM INTRAnet* site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive Zenocutuzumab.

- ☐ Interstitial Lung Disease or pneumonitis
- ☐ Clinically significant cardiac disease defined as: Baseline Left Ventricular Ejection Fraction < 50%, Uncontrolled hypertension or arrhythmia, Congestive Heart Failure (New York Heart Association Class 3 or 4)
- ☐ Platelets <75 X 10^9/L or Hemoglobin <9 grams/dL
- ☐ Absolute Neutrophil Count <1.5 x 10^9/L unless Duffy-null phenotype
- ☐ Total bilirubin > 1.5 X Upper Limit of Normal unless due to Gilbert's syndrome
- ☐ Creatine Clearance < 30ml/min
- ☐ Pregnancy
- ☐ Lactation

Additional Inclusion Criteria

One of the following criteria must be met:

- ☐ NRG1 gene fusion positive (RNA based sequencing preferred) Non-Small Cell Lung Cancer with progression on or after prior systemic therapy including platinum-based chemotherapy and/or targeted therapy if clinically indicated
- ☐ NRG1 gene fusion positive (RNA based sequencing preferred) advanced, unresectable, or metastatic pancreatic adenocarcinoma with progression on or after prior systemic therapy including fluoropyrimidine- and/or gemcitabine-based chemotherapy

Inclusion Criteria

All of the following criteria must be met:

- ☐ Care is provided by a VA/VA Community Care oncology provider
- ☐ Eastern Cooperative Oncology Group (ECOG) performance status 0-2
- ☐ Goals of care and role of Palliative Care consult have been discussed and documented

Additional Inclusion Criteria

- ☐ For females who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception during therapy and for 2 months after stopping treatment

Prepared: June 2025 by Brooke Wallace, PharmD. Contact: Mark Geraci PharmD, BCOP, National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services (12PBM)