

# Zolbetuximab-clzb (VYLOY)

## Criteria for Use

### March 2025

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

*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 PBM-MAP-VPE 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 zolbetuximab.

- PD-L1 by Combined Positive Score (CPS)  $\geq 5$  (unless patient is not a candidate for an immune checkpoint inhibitor)
- Prior severe allergic reaction or intolerance to known ingredients of zolbetuximab or other monoclonal antibodies, including humanized or chimeric antibodies
- Absolute Neutrophil Count  $\leq 1500/\text{mm}^3$
- Platelets  $\leq 100,000/\text{mm}^3$
- Total bilirubin  $\geq 1.5x$  Upper Limit of Normal (or  $> 3x$  Upper Limit of Normal with liver metastases)
- Estimated Creatinine Clearance  $\leq 30\text{ml}/\text{min}$
- Lactation

### Inclusion Criteria

All of the following criteria must be met.

- Locally advanced unresectable or metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma
- HER2-negative tumor
- CLDN18.2 positive tumor ( $\geq 75\%$  of tumor cells showing moderate-to-strong staining)
- Treatment plan includes zolbetuximab with a fluoropyrimidine- and platinum-based regimen (i.e. mFOLFOX6 or CAPOX) as first-line therapy
- Care is provided by a VA/VA Community Care oncology or hematology 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 *if applicable*

- For females who can become pregnant: Counseling provided on potential risks vs benefits of treatment; treatment should be given if the benefit outweighs the potential risk
- For females who are lactating: breastfeeding/providing breastmilk to an infant is not recommended during therapy and for 8 months after stopping treatment.

### Other Justification

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