Zolbetuximab-clzb (Vyloy®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:

POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Vyloy is indicated in combination with fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of adults with locally advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-negative gastric or gastroesophageal junction (GEJ) adenocarcinoma whose tumors are claudin (CLDN) 18.2 positive as determined by an FDA-approved test.

Compendial Uses

- Esophageal and esophagogastric junction cancers
- Gastric cancer

All other indications are considered experimental/investigational and not medically necessary.

DOCUMENTATION

Submission of CLDN18.2 and HER2 status is necessary to initiate the prior authorization review.

COVERAGE CRITERIA

Esophageal, Gastric, and Gastroesophageal Junction Adenocarcinoma

Authorization of 12 months may be granted for CLDN18.2-positive, HER2-negative esophageal, ~~locally advanced unresectable or metastatic~~ gastric, or GEJ adenocarcinoma when the member has unresectable, recurrent, or metastatic disease or is not a surgical candidate as first-line treatment, in combination with fluoropyrimidine- and platinum-containing chemotherapy.

CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication outlined in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Vyloy [package insert]. Northbrook, IL: Astellas Pharma US, Inc.; June 2025.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed July 14, 2025.

EFFECTIVE DATE

ID_CHS_2025