Anti-Neoplastics: Gastroesophageal
Vyloy (zolbetuximab-clzb) J1326
Prior Authorization Request
Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ New Start or Initial Request: (Clinical documentation required for all requests)

☐ CLDN18.2-Positive, HER2-Negative Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

☐ Patient has confirmed diagnosis of locally advanced unresectable or metastatic gastric or GEJ adenocarcinoma AND
☐ Tumor is HER2-negative (IHC 0, 1+, or IHC 2+/ISH-) AND
☐ Tumor is CLDN18.2-positive (moderate-to-strong membranous staining in ≥75% of tumor cells via validated IHC test) AND
☐ Patient has received no prior systemic therapy for metastatic disease (first-line treatment) AND
☐ Treatment is in combination with fluoropyrimidine- and platinum-based chemotherapy AND
☐ ECOG performance status 0-1 AND
☐ Prescribed by or in consultation with oncologist

If not, please provide **clinical rationale** for formulary exception: _____
_____

☐ Continuation Requests: (Clinical documentation required for all requests)

☐ Patient had an **adequate response** or **significant improvement** while on this medication.

☐ Medical record documentation of positive response is included

If not, please provide clinical rationale for continuing this medication: _____

_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Anti-Neoplastics: Gastroesophageal Prior Authorization

Drug Name(s):
VYLOY **ZOLBETUXIMAB-CLZB**

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Prescribed by, or in consultation with an oncologist or other cancer specialist related to the diagnosis.
3. Drug is being used appropriately per NCCN, CMS recognized compendia, authoritative medical literature, evidence based guidelines and/or accepted standards of medical practice.
4. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and tiering will be determined by the Plan, in accordance with the Label.

Exclusion Criteria:
N/A

Prescriber Restrictions:
Oncologist or other related specialist

Coverage Duration:
Approval will be for 6 months

FDA Indications:
Vyloy

- Gastric cancer, Adenocarcinoma, locally advanced or metastatic, HER2-negative, claudin 18.2 positive, first-line treatment in combination with fluoropyrimidine- and platinum-containing chemotherapy.
- Gastroesophageal junction cancer, Adenocarcinoma, locally advanced or metastatic, HER2-negative, claudin 18.2 positive, first-line treatment in combination with fluoropyrimidine- and platinum-containing chemotherapy

Off-Label Uses:
N/A

Age Restrictions:
The safety and effectiveness of zolbetuximab-clzb in pediatric patients have not been established

Other Clinical Consideration:
N/A

Resources:
https://www.micromedexsolutions.com/micromedex2/librarian/CS/310C32/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/D475F9/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=934551&contentSetId=100&title=Zolbetuximab-clzb&servicesTitle=Zolbetuximab-clzb&brandName=Vyloy&UserMdxSearchTerm=vyloy#