Medical Policy:

Vyloy® (zolbetuximab-clzb) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.418	December 12, 2024	December 12, 2024

Definitions

Vyloy, in combination with fluoropyrimidine- and platinum-containing chemotherapy, is indicated 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.

Length of Authorization

Coverage will be provided for 6 months and may be renewed.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time) [HCPCS Unit]:

- **First Dose:**
  - 2000 mg (20 vials) one time only
- **Subsequent Doses:**
  - 1500 mg (15 vials) every 3 weeks; **OR**

- 1000 mg (10 vials) every 2 weeks

Guideline

I. INITIAL CRITERIA

Coverage is provided in the following conditions:

1. Patient is at least 18 years of age; **AND**
2. Patient is not experiencing Grade 2 or greater nausea and/or vomiting prior to the first infusion; **AND**
3. Patient does not have a complete or partial gastric outlet syndrome; **AND**
4. Patient does not have a history of central nervous system metastases; **AND**
5. **Gastric, Gastro-Esophageal Junction Cancers † ‡ Φ**
   a. Patient has locally advanced unresectable, or metastatic adenocarcinoma; **AND**
   b. Used as first-line therapy; **AND**
   c. Patient has claudin (CLDN) 18.2-positive (defined as ≥75% of tumor cells demonstrating moderate to strong membranous CLDN1 immunohistochemical staining) disease as determined by an FDA-approved or CLIA-compliant test; **AND**
   d. Patient has human epidermal growth factor receptor 2 (HER2)-negative disease; **AND**
   e. Used in combination with a fluoropyrimidine- and platinum-containing chemotherapy-based regimen

II. RENEWAL CRITERIA

Coverage may be renewed based upon the following criteria:

1. Patient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in Initial Criteria; **AND**
2. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
3. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe hypersensitivity reactions including anaphylaxis, severe nausea and vomiting, etc.

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

Applicable Procedure Codes

Code	Description
J9999	Not otherwise classified, antineoplastic drugs
C9399	Unclassified drugs or biologicals (hospital outpatient use)

Applicable NDCs

Code	Description
00469-3425-xx	Vyloy 100 mg powder in a single-dose vial

ICD-10 Diagnoses

Code	Description
C15.3	Malignant neoplasm of upper third of esophagus
C15.4	Malignant neoplasm of middle third of esophagus
C15.5	Malignant neoplasm of lower third of esophagus
C15.8	Malignant neoplasm of overlapping sites of esophagus

C15.9	Malignant neoplasm of esophagus, unspecified
C16.0	Malignant neoplasm of cardia
C16.1	Malignant neoplasm of fundus of stomach
C16.2	Malignant neoplasm of body of stomach
C16.3	Malignant neoplasm of pyloric antrum
C16.4	Malignant neoplasm of pylorus
C16.5	Malignant neoplasm of lesser curvature of stomach, unspecified
C16.6	Malignant neoplasm of greater curvature of stomach, unspecified
C16.8	Malignant neoplasm of overlapping sites of stomach
C16.9	Malignant neoplasm of stomach, unspecified
D37.1	Neoplasm of uncertain behavior of stomach
D37.8	Neoplasm of uncertain behavior of other specified digestive organs
D37.9	Neoplasm of uncertain behavior of digestive organ, unspecified
Z85.00	Personal history of malignant neoplasm of unspecified digestive organ
Z85.01	Personal history of malignant neoplasm of esophagus
Z85.028	Personal history of other malignant neoplasm of stomach

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	12/12/2024	New Policy

References

1. Vyloy [package insert]. Northbrook, IL; Astellas Pharma US, Inc.; October 2024. Accessed October 2024