Mass General Brigham
Health Plan

Oncology Immunotherapies
Vyloy (zolbetuximab-clzb)
Effective 04/03/2025

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview
Vyloy (zolbetuximab-clzb), 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.

Coverage Guidelines
Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members when all the following criteria are met:

1. Diagnosis of locally advanced unresectable or metastatic HER-2- negative gastric or gastroesophageal junction adenocarcinoma
2. Member is ≥18 years of age
3. Prescriber is an oncologist
4. Tumor expresses CLDN18.2
5. Requested agent will be used in combination with **BOTH** of the following:
   a. Fluoropyrimidine-containing chemotherapy
   b. Platinum-containing chemotherapy
6. Appropriate dosing

Continuation of Therapy
Resubmission by prescriber will infer a positive response to therapy.

Limitations

1. Initial approvals will be granted for 6 months
2. Reauthorizations will be granted for 12 months.

References

1. Vyloy [package insert] Northbrook (IL): Astellas Pharma US, Inc.; 2024 Oct.

Review History

03/12/25 – Created for P&T. Adopted MH criteria. New drug will be managed through medical benefit only. Effective 4/3/25