| Reference number(s) |
| --- |
| 6704-A |

# Standard Medicare Part B Management
# Vyloy

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Vyloy | zolbetuximab-clzb |

## 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[1]

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[2]

- Esophageal and esophagogastric junction cancers
- Gastric cancer

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.


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# Documentation

The following documentation must be available, upon request, for all submissions: CLDN18.2 and HER2 status.

# Coverage Criteria

## Esophageal, Gastric, and Gastroesophageal Junction Adenocarcinoma[1,2]

Authorization of 12 months may be granted for CLDN18.2-positive, HER2-negative esophageal, 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

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested medication.

Authorization of 12 months may be granted when all of the following criteria are met:

- The member is currently receiving treatment with the requested medication.
- The requested medication is being used to treat a diagnosis or condition listed in the coverage criteria section.
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen AND
    - No evidence of disease progression while on the current regimen.

# Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Vyloy.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: Esophageal and Esophagogastric Junction Cancers


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- NCCN Guideline: Gastric Cancer

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Vyloy are covered in addition to esophageal and esophagogastric junction cancer.

# Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Vyloy to treat esophageal and esophagogastric junction cancer can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

# 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.


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