Reference number(s)
6703-A

Specialty Guideline 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

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.

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.

Reference number(s)
6703-A

Coverage Criteria

Gastric and Gastroesophageal Junction Adenocarcinoma[1]

Authorization of 12 months may be granted for CLDN18.2-positive, HER2-negative locally advanced unresectable or metastatic gastric or GEJ adenocarcinoma 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.

References

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