

PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Vyloy Prior Authorization Policy

- Vyloy® (zolbetuximab-clzb intravenous infusion – Astellas)

REVIEW DATE: 10/30/2024

OVERVIEW

Vyloy, a claudin 18.2-directed cytolytic antibody, is indicated in combination with fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of locally advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-negative gastric or gastrointestinal junction adenocarcinoma in adults in whose tumors are claudin 18.2 positive as determined by an FDA-approved test.¹

Guidelines

The National Comprehensive Cancer Network has not addressed Vyloy.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Vyloy. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Vyloy as well as the monitoring required for adverse events and long-term efficacy, approval requires Vyloy to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Vyloy is recommended in those who meet the following criteria:

FDA-Approved Indication

- 1. Gastric or Gastroesophageal Junction Adenocarcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, E, F, and G):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has locally advanced unresectable or metastatic disease; AND
 - C) Tumor is claudin 18.2 positive as determined by an approved test; AND
Note: Claudin 18.2 positivity is defined as $\geq 75\%$ of tumor cells demonstrating moderate to strong membranous claudin 18.2 immunohistochemical staining.
 - D) Tumor is human epidermal growth factor receptor 2 (HER2)-negative; AND
 - E) Medication is used for first-line treatment; AND
 - F) Medication is used in combination with fluoropyrimidine- and platinum-containing chemotherapy; AND
Note: Examples of fluoropyrimidines include 5-fluorouracil and capecitabine. Examples of platinum chemotherapy agents include oxaliplatin.
 - G) Medication is prescribed by or consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

10/30/2024

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Coverage of Vyloy is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Vyloy intravenous infusion [prescribing information]. Northbrook, IL: Astellas; October 2024.