

In advanced* G/GEJ cancer,

Detect CLDN18.2 and reveal a predictive biomarker for a targeted therapy.^{1,2}

*Locally advanced unresectable or metastatic.¹

CLDN18.2=claudin 18.2; G/GEJ=gastric/gastroesophageal junction.



INDICATION

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.

SELECT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hypersensitivity reactions, including serious anaphylaxis reactions, and serious and fatal infusion-related reactions (IRR) have been reported in clinical studies when VYLOY has been administered. **Any grade hypersensitivity reactions**, including anaphylactic reactions, occurring with VYLOY in combination with mFOLFOX6 or CAPOX was 18%. **Severe (Grade 3 or 4) hypersensitivity reactions**, including anaphylactic reactions, occurred in 2% of patients. Seven patients (1.3%) permanently discontinued VYLOY for hypersensitivity reactions, including two patients (0.4%) who permanently discontinued VYLOY due to anaphylactic reactions. Seventeen (3.2%) patients required dose interruption, and three patients (0.6%) required infusion rate reduction due to hypersensitivity reactions. **All grade IRRs** occurred in 3.2% in patients administered VYLOY in combination with mFOLFOX6 or CAPOX. Severe (Grade 3) IRRs occurred in 2 (0.4%) patients who received VYLOY. An IRR led to permanent discontinuation of VYLOY in 2 (0.4%) patients and dose interruption in 7 (1.3%) patients. The infusion rate was reduced for VYLOY for 2 (0.4%) patients due to an IRR. Monitor patients during infusion with VYLOY and for 2 hours after completion of infusion or longer if clinically indicated, for hypersensitivity reactions with symptoms and signs that are highly suggestive of anaphylaxis (urticaria, repetitive cough, wheeze and throat tightness/change in voice). Monitor patients for signs and symptoms of IRRs including nausea, vomiting, abdominal pain, salivary hypersecretion, pyrexia, chest discomfort, chills, back pain, cough and hypertension. If a severe or life-threatening hypersensitivity or IRR reaction occurs, discontinue VYLOY permanently, treat symptoms according to standard medical care, and monitor until symptoms resolve. For any Grade 2 hypersensitivity or IRR, interrupt the VYLOY infusion until Grade ≤ 1 , then resume at a reduced infusion rate for the remaining infusion. Follow Grade 2 management for Grade 3 infusion-related nausea and vomiting. Premedicate the patient with antihistamines for the subsequent infusions, and closely monitor the patient for symptoms and signs of a hypersensitivity reaction. The infusion rate may be gradually increased as tolerated.

Please see Important Safety Information throughout and on page 6, and full Prescribing Information.

VYLOY®
zolbetuximab-clzb
for injection 100mg and 300mg vials

According to estimates from two global Phase 3 studies:

38% of patients with advanced* G/GEJ adenocarcinoma are CLDN18.2+^{3,4†‡}

Data estimated from 2 global randomized Phase 3 studies: SPOTLIGHT, which included 2,403 assessable patients, of which 922 were CLDN18.2 positive; and GLOW, which included 2,104 assessable patients, of which 808 were CLDN18.2 positive as determined by IHC in a central laboratory using the investigational VENTANA CLDN18 (43-14A) RxDx Assay.^{3,4}

Claudin 18.2 is one of the most highly prevalent biomarkers in advanced G/GEJ adenocarcinoma³⁻¹³

Biomarker prevalence estimates from select studies are reported below. Prevalence data can vary among studies due to tumor heterogeneity, differences in patient population, clinical trial methodology, and diagnostic assays used.³⁻¹³

CLDN18.2 ^{3,4} (positive) ^{†‡}	PD-L1 ^{5,9-12} (variable due to multiple factors) [§]	HER2 ⁶⁻⁸ (positive)	MMR or MSI ¹¹⁻¹³ (MSI-high)
38%	CPS ≥1: 67-82% CPS ≥5: 29-60% CPS ≥10: 16-49%	14-22%	3-7%

Published studies have shown no significant correlation between CLDN18.2 positivity and the expression of biomarkers such as PD-L1, MMR/MSI, and HER2.¹⁴⁻¹⁶

*Locally advanced unresectable or metastatic.^{3,4}

† CLDN18.2+ (claudin 18.2 positive) is defined as ≥75% of tumor cells demonstrating moderate to strong membranous CLDN18 staining by IHC.^{3,4}

‡ Data from 2 global randomized Phase 3 studies: SPOTLIGHT, which included 2,403 assessable patients, of which 922 were CLDN18.2 positive; and GLOW, which included 2,104 assessable patients, of which 808 were CLDN18.2 positive.^{3,4}

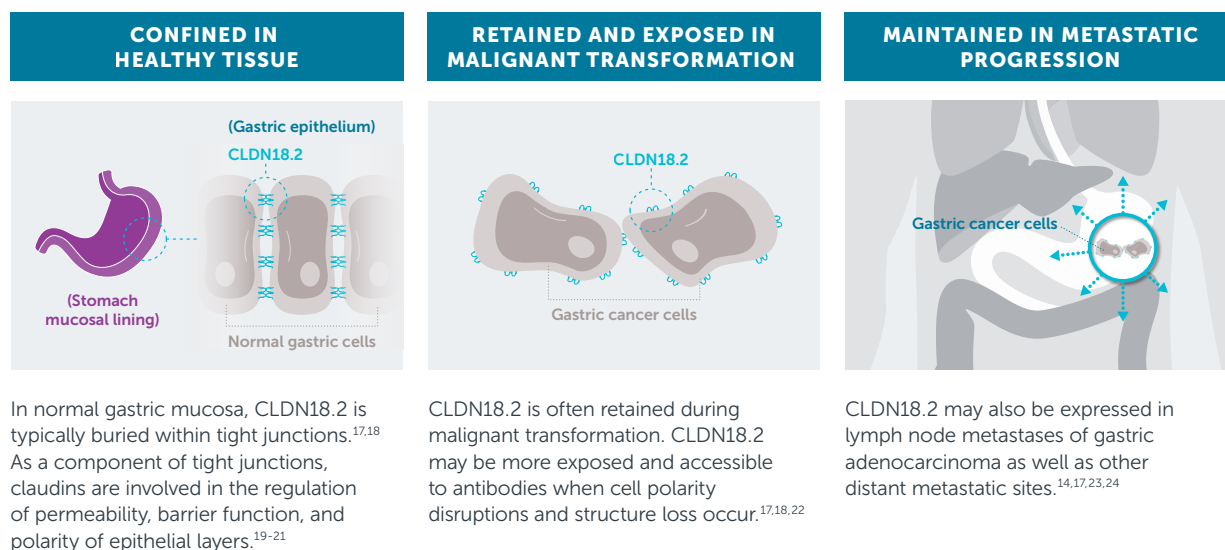
§ CPS thresholds are still being explored. Data are from randomized controlled trials and real-world retrospective medical records studies.^{5,9-12}

|| MSI-high prevalence varies by stage of disease. Data shown are from patients with advanced disease.¹¹⁻¹³

CPS=combined positive score; IHC=immunohistochemistry; MMR=mismatch repair; MSI=microsatellite instability; PD-L1=programmed death-ligand 1.

Claudin 18.2 is a predictive and actionable biomarker in gastric tumors^{1,2*}

CLDN18.2 is typically confined within healthy gastric mucosa; however, it may become exposed, and thus more accessible to VYLOY as tumors develop.^{17,18}



- Claudins are found throughout the body, but CLDN18.2 is the dominant CLDN18 isoform in gastric tissue^{17,25}
- VYLOY specifically targets CLDN18.2¹

*Advanced G/GEJ adenocarcinoma.¹

VYLOY IS AN FDA-APPROVED FIRST-LINE TREATMENT THAT TARGETS CLAUDIN 18.2

SELECT SAFETY INFORMATION WARNINGS AND PRECAUTIONS

Severe Nausea and Vomiting. VYLOY is emetogenic. Nausea and vomiting occurred more often during the first cycle of treatment. **All grade nausea and vomiting** occurred in 82% and 67% respectively of patients treated with VYLOY in combination with mFOLFOX6 and 69% and 66% in combination with CAPOX, respectively. **Severe (Grade 3) nausea** occurred in 16% and 9% of patients treated with VYLOY in combination with mFOLFOX6 or CAPOX respectively. **Severe (Grade 3) vomiting** occurred in 16% and 12% of patients treated with VYLOY in combination with mFOLFOX6 or CAPOX. Nausea led to permanent discontinuation of VYLOY in combination with mFOLFOX6 or CAPOX in 18 (3.4%) patients and dose interruption in 147 (28%) patients. Vomiting led to permanent discontinuation of VYLOY in combination with mFOLFOX6 or CAPOX in 20 (3.8%) patients and dose interruption in 150 (28%) patients. Pretreat with antiemetics prior to each infusion of VYLOY. Manage patients during and after infusion with antiemetics or fluid replacement. Interrupt the infusion, or permanently discontinue VYLOY based on severity.

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NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) recommend CLDN18.2 testing at the time of diagnosis if advanced/metastatic disease/adenocarcinoma is documented/suspected^{26,27*}

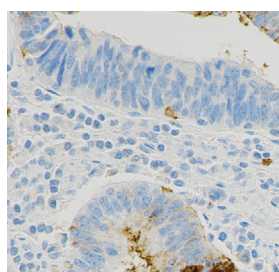
*This is a summary of relevant portions of the NCCN Guidelines. Please see the full NCCN Guidelines for Gastric Cancer and Esophageal and Esophagogastric Junction Cancers at [NCCN.org](https://www.nccn.org).^{26,27}

The VENTANA CLDN18 (43-14A) RxDx Assay is FDA-approved as a companion diagnostic to identify patients for a first-line targeted treatment²⁸

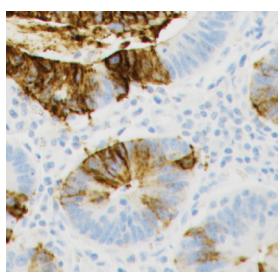
- This assay is used with OptiView DAB IHC Detection Kit for staining on a BenchMark ULTRA instrument

CLDN18.2 IS EVALUATED USING BOTH MEMBRANOUS STAINING INTENSITY AND PERCENTAGE OF VIABLE TUMOR CELLS STAINED²⁸

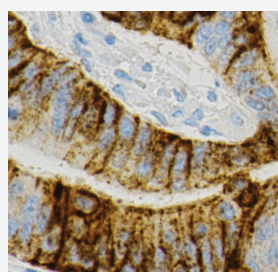
Membrane staining of tumor cells²⁹



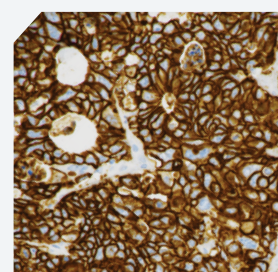
**NO
STAINING**



**WEAK
STAINING**



**MODERATE
STAINING**



**STRONG
STAINING**

[†]Test results of the VENTANA CLDN18 (43-14A) RxDx Assay should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls.²⁸

VENTANA CLDN18 (43-14A) RxDx Assay and BenchMark ULTRA are registered trademarks of Roche Diagnostics.

The clinical cutoff is $\geq 75\%$ viable tumor cells demonstrating moderate-to-strong membranous CLDN18 staining above background.^{28†}

Testing is available throughout the United States



FIND TESTING SITES THAT OFFER THE VENTANA CLDN18 (43-14A) RXDX ASSAY AT [VYLOYHCP.COM](https://www.vyloymh.com)

Explore resources to help you begin testing



Assay Education

Learn how to detect CLDN18.2+ cells in G/GEJ tumors with the VENTANA CLDN18 (43-14A) Rx Dx Assay.^{1,28} Explore the eLearning Module on cancerdiagnosticeducation.com.



Expand your lab's test offerings

Visit go.roche.com/CLDN18 to learn more about the FDA-approved assay indicated to help identify patients who may be candidates for VYLOY + chemo.^{1,28}

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IMPORTANT SAFETY INFORMATION

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ADVERSE REACTIONS

Most common adverse reactions ($\geq 15\%$): Nausea, vomiting, fatigue, decreased appetite, diarrhea, peripheral sensory neuropathy, abdominal pain, constipation, decreased weight, hypersensitivity reactions, and pyrexia.

Most common laboratory abnormalities ($\geq 15\%$): Decreased neutrophil count, decreased leucocyte count, decreased albumin, increased creatinine, decreased hemoglobin, increased glucose, decreased lymphocyte count, increased aspartate aminotransferase, decreased platelets, increased alkaline phosphatase, increased alanine aminotransferase, decreased glucose, decreased sodium, decreased phosphate, decreased potassium, and decreased magnesium.

SPOTLIGHT Study: 279 patients with locally advanced unresectable or metastatic HER2-negative gastric or GEJ adenocarcinoma whose tumors were CLDN18.2 positive who received at least one dose of VYLOY in combination with mFOLFOX6

Serious adverse reactions occurred in 45% of patients treated with VYLOY in combination with mFOLFOX6; the **most common serious adverse reactions** ($\geq 2\%$) were vomiting (8%), nausea (7%), neutropenia (2.9%), febrile neutropenia (2.9%), diarrhea (2.9%), intestinal obstruction (3.2%), pyrexia (2.5%), pneumonia (2.5%), respiratory failure (2.2%), pulmonary embolism (2.2%), decreased appetite (2.1%) and sepsis (2.0%). **Fatal adverse reactions** occurred in 5% of patients who received VYLOY in combination with mFOLFOX6 including sepsis (1.4%), pneumonia (1.1%), respiratory failure (1.1%), intestinal obstruction (0.7%), acute hepatic failure (0.4%), acute myocardial infarction (0.4%), death (0.4%), disseminated intravascular coagulation (0.4%), encephalopathy (0.4%), and upper gastrointestinal hemorrhage (0.4%). Permanent discontinuation of VYLOY due to an adverse reaction occurred in 20% of patients; the **most common adverse reactions leading to discontinuation** ($\geq 2\%$) were nausea and vomiting. Dosage interruptions of VYLOY due to an adverse reaction occurred in 75% of patients; the **most common adverse reactions leading to dose interruption** ($\geq 5\%$) were nausea, vomiting, neutropenia, abdominal pain, fatigue, and hypertension.

GLOW Study: 254 patients with locally advanced unresectable or metastatic HER2-negative gastric or GEJ adenocarcinoma whose tumors were CLDN18.2 positive who received at least one dose of VYLOY in combination with CAPOX

Serious adverse reactions occurred in 47% of patients treated with VYLOY in combination with CAPOX; the **most common serious adverse reactions** ($\geq 2\%$) were vomiting (6%), nausea (4.3%), decreased appetite (3.9%), decreased platelet count (3.1%), upper gastrointestinal hemorrhage (2.8%), diarrhea (2.8%), pneumonia (2.4%), pulmonary embolism (2.3%), and pyrexia (2.0%). **Fatal adverse reactions** occurred in 8% of patients who received VYLOY in combination with CAPOX including sepsis (1.2%), pneumonia (0.4%), death (0.8%), upper gastrointestinal hemorrhage (0.8%), cerebral hemorrhage (0.8%), abdominal infection (0.4%), acute respiratory distress syndrome (0.4%), cardio-respiratory arrest (0.4%), decreased platelet count (0.4%), disseminated intravascular coagulation (0.4%), dyspnea (0.4%), gastric perforation (0.4%), hemorrhagic ascites (0.4%), procedural complication (0.4%), sudden death (0.4%), and syncope (0.4%). Permanent discontinuation of VYLOY due to an adverse reaction occurred in 19% of patients; the **most common adverse reaction leading to discontinuation** ($\geq 2\%$) was vomiting. Dosage interruption of VYLOY due to an adverse reaction occurred in 55% of patients; the **most common adverse reactions leading to dose interruption** ($\geq 2\%$) were nausea, vomiting, neutropenia, thrombocytopenia, anemia, fatigue, infusion-related reaction, and abdominal pain.

Post Marketing Experience: Gastrointestinal disorders: gastritis, protein-losing gastroenteropathy adverse reactions have been identified during post-approval use of VYLOY. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

SPECIFIC POPULATIONS

Lactation Advise lactating women not to breastfeed during treatment with VYLOY and for 8 months after the last dose.

Please see full Prescribing Information.



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VYLOY
zolbetuximab-clzb
for injection 100mg and 300mg vials

