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

Epic® Electronic Health Record (EHR) System Order Set Instructions for VYLOY® (zolbetuximab-clzb)

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INDICATION

VYLOY, 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 click here for additional Important Safety Information and click here for full Prescribing Information.

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Indication and Important Safety Information

INDICATION

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IMPORTANT SAFETY INFORMATION

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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.

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.

Please see additional Important Safety Information on next page and click here for full Prescribing Information.

Important Safety Information (cont'd)

ADVERSE REACTIONS

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

Most common laboratory abnormalities (≥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 (zolbetuximab-clzb) 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** (≥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** (≥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** (≥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** (≥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** (≥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** (≥2%) were nausea, vomiting, neutropenia, thrombocytopenia, anemia, fatigue, infusion-related reaction, and abdominal pain.

SPECIFIC POPULATIONS

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

Please click here for full Prescribing Information.

1. Background and Considerations

This document is intended to provide instructions to manually add VYLOY (zolbetuximab-clzb) as an additional treatment option for human epidermal growth factor receptor 2-negative (HER2–), CLDN18.2-positive (CLDN18.2+) locally advanced unresectable or metastatic gastric/gastroesophageal junction (G/GEJ) adenocarcinoma within the approved indication that is consistent with the Prescribing Information.

EHRs may assist providers in identifying appropriate patients for assessment, treatment, and/or referral. Decisions and actions should be decided by a provider in consultation with the patient and after a review of the patient's records to determine eligibility.

This guide includes information such as the indication, important dosing information, and dosing modifications; however, this document is not fully inclusive of all details of the VYLOY Prescribing Information. The clinical data elements are suggestions only. The customer must determine the final elements to include in line with the organization's expectations, goals, and EHR governing principles.

The customer is solely responsible for implementing, testing, and monitoring these instructions and the information included in the customer's EHR system.

Please consult the most recent version of the VYLOY Prescribing Information for full medication details. The most recent version of the VYLOY Prescribing Information may be found at https://www.astellas.com/us/system/files/vyloy_pi.pdf.

Indication

VYLOY, 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.

Patient selection

Select adult patients with locally advanced unresectable or metastatic HER2-negative gastric or GEJ adenocarcinoma whose tumors are CLDN18.2 positive (defined as ≥75% of tumor cells demonstrating moderate to strong membranous CLDN18 immunohistochemical staining) for treatment with VYLOY in combination with fluoropyrimidine- and platinum-containing chemotherapy using an FDA-approved test.

Information on FDA-approved tests for the detection of CLDN18.2 is available at: http://www.fda.gov/CompanionDiagnostics.

FDA, U.S. Food and Drug Administration.

Please click here for Important Safety Information and click here for full Prescribing Information.

1. Background and Considerations (cont'd)

Prior to administration

If a patient is experiencing nausea and/or vomiting prior to administration of VYLOY (zolbetuximab-clzb), the symptoms should be resolved to Grade ≤1 before administering the first infusion.

Premedication

Prior to each infusion of VYLOY, premedicate patients with a combination of antiemetics (eg, NK-1 receptor blockers and/or 5-HT_3 receptor blockers, as well as other drugs as indicated) for the prevention of nausea and vomiting *[see Warnings and Precautions (5.2)]*.

Recommended dosage

Administer VYLOY in combination with fluoropyrimidine- and platinum-containing chemotherapy as follows:

- First dose: 800 mg/m^2 intravenously
- Subsequent doses:
  - 600 mg/m^2 intravenously every 3 weeks, or
  - 400 mg/m^2 intravenously every 2 weeks
- Continue treatment until disease progression or unacceptable toxicity
- The frequency of subsequent doses should be selected to align with chemotherapy backbone

Dosage modifications for adverse reactions

No dose reduction for VYLOY is recommended. Adverse reactions for VYLOY are managed by reducing the infusion rate, interruption of the infusion, withholding the dose, and/or permanently discontinuing VYLOY as described in Table 1.

Table 1: Recommended dose modifications for VYLOY for adverse reactions

Adverse reaction	Severity*	Dose modification
Hypersensitivity or infusion-related reactions *[see Warnings and Precautions (5.1)]*	Grade 2	• Interrupt the infusion until Grade ≤1, then resume at a reduced infusion rate for the remaining infusion • Premedicate and administer the next infusion per the infusion rates as described in the full Prescribing Information
	Grade 3† or 4 or anaphylaxis	Immediately stop the infusion and permanently discontinue.

*Toxicity was graded per National Cancer Institute Common Terminology Criteria for Adverse Events Version 5.0 (NCI-CTCAE v5.0).
†Follow Grade 2 management for Grade 3 infusion-related nausea and vomiting.

Storage of diluted infusion

Store the prepared infusion bag:

- At room temperature 15°C to 30°C (59°F to 86°F) for no longer than 6 hours from the end of the preparation of the infusion bag to the completion of the infusion.
- Under refrigeration at 2°C to 8°C (36°F to 46°F) for no longer than 16 hours from the end of the preparation of the infusion bag to the completion of the infusion. Do not freeze.

5-HT_3, 5-hydroxytryptamine; **NK-1,** neurokinin-1.

Please click here for Important Safety Information and click here for full Prescribing Information.

1. Background and Considerations (cont'd)

Additional information

- Instructions for preparation: see section 2.5 of the Prescribing Information
- Instructions for administration: see section 2.6 of the Prescribing Information

Dosage forms and strengths

For injection: 100 mg and 300 mg of zolbetuximab-clzb as a white to off-white lyophilized powder in a single-dose vial for reconstitution.

VYLOY (zolbetuximab-clzb) vials are available in the following packages:

- Carton of one 100 mg single-dose vial (NDC: 0469-3425-10)
- Carton of one 300 mg single-dose vial (NDC: 0469-4425-30)

Helpful links:

VYLOY full Prescribing Information	https://www.astellas.com/us/system/files/vyloy_pi.pdf
VYLOY Patient Website	https://www.vyloy.com
Patient Education Resources	https://www.vyloy.com/resources
VYLOY Support Solutions℠ Website	https://vyloysupportsolutions.com
VYLOY HCP Website	https://www.vyloyhcp.com
HCP Support Materials	https://www.vyloyhcp.com/access-and-resources
NCCN Clinical Guidelines in Oncology (NCCN Guidelines®)	**Gastric Cancer:** https://www.nccn.org/guidelines/guidelines-detail?category=1&id=1434 **Esophageal and Esophagogastric Junction Cancers:** https://www.nccn.org/guidelines/guidelines-detail?category=1&id=1433

HCP, healthcare provider; **NDC,** National Drug Code.

Please click here for Important Safety Information and click here for full Prescribing Information.

2. Epic Instructions

Updating Beacon protocols in the Epic EHR system requires 2 steps (and 1 optional step)

1. Creation of order groups to hold the VYLOY (zolbetuximab-clzb) order groups with the different dosing options, the VYLOY Monitoring and Hold Parameters, VYLOY Important Safety Information, and VYLOY premedication details
   Optional: Consider adding the VYLOY package insert links to the medication record
2. Adding the order groups to the Beacon protocol

Creating the order groups

- Review the **Regimen Category Order Group** to confirm **Medications** is a value in the category list
- Consider adding the following information:

Order Group 1 **VYLOY first dose: 800 mg/m²**

- Complete the VYLOY medication details (800 mg/m² intravenously)
- Administer VYLOY in combination with fluoropyrimidine- and platinum-containing chemotherapy
- If VYLOY and fluoropyrimidine- and platinum-containing chemotherapy are administered on the same day, VYLOY must be administered first
- Continue treatment until disease progression or unacceptable toxicity
- Infusion rates
  - Initial infusion rate (first 30-60 minutes): 100 mg/m²/hr*
  - Subsequent infusion rate: 200-265 mg/m²/hr
- For patient selection, prior to administration and premedication details, dose modifications for adverse reactions, preparation, administration, and infusion bag and infusion rate recommendations for VYLOY, refer to https://www.astellas.com/us/system/files/vyloy_pi.pdf

Order Group 2 **VYLOY (zolbetuximab-clzb) subsequent dose (option 1): 400 mg/m² intravenously every 2 weeks**

- Complete the VYLOY medication details (400 mg/m² intravenously every 2 weeks)
- Administer VYLOY in combination with fluoropyrimidine- and platinum-containing chemotherapy
- If VYLOY and fluoropyrimidine- and platinum-containing chemotherapy are administered on the same day, VYLOY must be administered first
- Continue treatment until disease progression or unacceptable toxicity
- Infusion rates
  - Initial infusion rate (first 30-60 minutes): 50 mg/m²/hr*
  - Subsequent infusion rate: 100-200 mg/m²/hr
- The frequency of subsequent doses should be selected to align with chemotherapy backbone
- For patient selection, prior to administration and premedication details, dose modifications for adverse reactions, preparation, administration, and infusion bag and infusion rate recommendations for VYLOY, refer to https://www.astellas.com/us/system/files/vyloy_pi.pdf

*In the absence of adverse reactions after 30-60 minutes, the infusion rate can be increased to the subsequent infusion rate as tolerated.

2. Epic Instructions (cont'd)

Order Group 3 **VYLOY subsequent dose (option 2): 600 mg/m² intravenously every 3 weeks**

- Complete the VYLOY medication details (600 mg/m² intravenously every 3 weeks)
- Administer VYLOY in combination with fluoropyrimidine- and platinum-containing chemotherapy
- If VYLOY and fluoropyrimidine- and platinum-containing chemotherapy are administered on the same day, VYLOY must be administered first
- Continue treatment until disease progression or unacceptable toxicity
- Infusion rates
  - Initial infusion rate (first 30-60 minutes): 75 mg/m²/hr*
  - Subsequent infusion rate: 150-265 mg/m²/hr
- The frequency of subsequent doses should be selected to align with chemotherapy backbone
- For patient selection, prior to administration and premedication details, dose modifications for adverse reactions, preparation, administration, and infusion bag and infusion rate recommendations for VYLOY, refer to https://www.astellas.com/us/system/files/vyloy_pi.pdf

*In the absence of adverse reactions after 30-60 minutes, the infusion rate can be increased to the subsequent infusion rate as tolerated.

Order Group 4 **VYLOY treatment conditions (alternatively, consider monitoring and hold parameters)**

Consider adding the following information:

Recommended dosing

- Administer VYLOY in combination with fluoropyrimidine- and platinum-containing chemotherapy as follows:
  - First dose: 800 mg/m² intravenously
  - Subsequent doses:
    - 600 mg/m² intravenously every 3 weeks, or
    - 400 mg/m² intravenously every 2 weeks
  - Continue treatment until disease progression or unacceptable toxicity

Dosage modifications for adverse reactions

No dose reduction for VYLOY is recommended. Adverse reactions for VYLOY are managed by reducing the infusion rate, interruption of the infusion, withholding the dose, and/or permanently discontinuing VYLOY as described in Table 1.

Table 1: Recommended dose modifications for VYLOY for adverse reactions

Adverse reaction	Severity†	Dose modification
Hypersensitivity or infusion-related reactions *[see Warnings and Precautions (5.1)]*	Grade 2	• Interrupt the infusion until Grade ≤1, then resume at a reduced infusion rate for the remaining infusion • Premedicate and administer the next infusion per the infusion rates as described in the full Prescribing Information
	Grade 3‡ or 4 or anaphylaxis	Immediately stop the infusion and permanently discontinue.

†Toxicity was graded per NCI-CTCAE v5.0.
‡Follow Grade 2 management for Grade 3 infusion-related nausea and vomiting

Please click here for Important Safety Information and click here for full Prescribing Information.

2. Epic Instructions (cont'd)

Order Group 4 **VYLOY (zolbetuximab-clzb) treatment conditions (alternatively, consider monitoring and hold parameters)**

(cont'd)

Table 2: Infusion rates recommended for each VYLOY infusion

VYLOY dose		Initial infusion rate (first 30-60 minutes)*	Subsequent infusion rate
First dose	800 mg/m^2	100 mg/m^2/hr	200-265 mg/m^2/hr
Subsequent doses	600 mg/m^2 every 3 weeks or 400 mg/m^2 every 2 weeks	75 mg/m^2/hr or 50 mg/m^2/hr	150-265 mg/m^2/hr or 100-200 mg/m^2/hr

*In the absence of adverse reactions after 30 to 60 minutes, the infusion rate can be increased to the subsequent infusion rate as tolerated.

Order Group 5 **VYLOY Important Safety Information**

Consider adding the following information:

- *See section 5* of the VYLOY Prescribing Information for Warnings and Precaution (Hypersensitivity reactions, including anaphylaxis reactions, and infusion related reactions, severe nausea and vomiting): https://www.astellas.com/us/system/files/vyloy_pi.pdf
- *See section 6* of the VYLOY Prescribing Information for Adverse Reactions: https://www.astellas.com/us/system/files/vyloy_pi.pdf
- See section 8.2 of the VYLOY Prescribing Information for Lactation: https://www.astellas.com/us/system/files/vyloy_pi.pdf

Order Group 6 **VYLOY premedication**

Consider adding the following information and add any desired medications:

- Prior to each infusion of VYLOY, premedicate patients with a combination of antiemetics (eg, NK-1 receptor blockers and/or 5-HT_3 receptor blockers, as well as other drugs as indicated) for the prevention of nausea and vomiting [*see Warnings and Precautions (5.2)*]: https://www.astellas.com/us/system/files/vyloy_pi.pdf
- VYLOY may cause severe nausea and vomiting. Please refer to nausea and vomiting guidelines.

Optional: Consider adding the VYLOY package insert link to the medication record

- Access the **Medication Master File (ERX)**
- Use the Medication Master File to search and select **VYLOY**
- On the **Patient Medication References Screen**, a link to the VYLOY Prescribing Information can be added
- Row 1: For **Display Name**, enter "**Package Insert**"
  - In the URL field, enter this hyperlink: https://www.astellas.com/us/system/files/vyloy_pi.pdf

Please click here for Important Safety Information and click here for full Prescribing Information.

2. Epic Instructions (cont'd)

Add the Order Groups to the Beacon protocol for first-line treatment of patients with locally advanced unresectable or metastatic HER2– G/GEJ adenocarcinoma whose tumors are CLDN18.2+.

The considerations below describe high level steps to add Order Groups to a new Beacon protocol with VYLOY (zolbetuximab-clzb) and its indication:

- Access the Protocol Builder functionality. It is recommended to search the existing catalog of regimens by using the search query "gastric," "gastroesophageal junction," or "GEJ." Note that an existing VYLOY order set may be available to optimize
  - The existing order set could serve as a template for the new VYLOY regimen. Consider retiring or removing the original regimen from the EHR production system according to the customer's EHR governing principles
- Once the regimen has been selected, the order groups can be added to the desired treatment calendar:
  - **First dose:**
    - 800 mg/m^2 intravenously
  - **Subsequent doses:**
    - 600 mg/m^2 intravenously every 3 weeks
      OR
    - 400 mg/m^2 intravenously every 2 weeks
  - Continue treatment until disease progression or unacceptable toxicity
- Add any other desired Order Groups, including but not limited to
  - **VYLOY Treatment Conditions**
  - **VYLOY Warnings and Precautions**
  - **VYLOY Premedication**
- Consider updating the Beacon protocol description to reflect the addition of VYLOY:
  - **VYLOY, 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**
- Once all information is completed, the regimen can be saved and released after satisfactory testing has been completed

Please click here for Important Safety Information and click here for full Prescribing Information.

3. Notes

After completing the VYLOY (zolbetuximab-clzb) order set process, a new VYLOY order set will be available. If the original order set used to create or update the new VYLOY order set included VYLOY, confirm the original order set is removed from the EHR system according to the customer's EHR governing principles.

Capabilities, functionality, and set-up (customization) for each individual EHR system vary. Astellas Pharma US, Inc. is not responsible for revising the implementation instructions if a customer modifies or changes its software, or for the configuration of its EHR system after such time as the implementation instructions have been initially provided by Astellas Pharma US, Inc.

While Astellas Pharma US, Inc. tests the implementation instructions on multiple EHR systems, they are not guaranteed to work for all available EHR systems, and customers are responsible for determining whether the instructions are applicable to the customer's EHR system.

This document has not been designed and is not a tool and/or solution for meeting any quality/accreditation requirements, including, but not limited to Advanced Care Information.

Reference: VYLOY. Package insert. Northbrook, IL: Astellas Pharma US, Inc; 2025.

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