

# Oracle Health<sup>®</sup> (previously Cerner) **Electronic Health Record (EHR) System** Order Set Instructions for VYLOY<sup>®</sup> (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  $\leq 1$ , 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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Please [click here](#) for additional Important Safety Information and [click here](#) for full Prescribing Information.

# Indication and Important Safety Information

## 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.

## IMPORTANT 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  $\leq 1$ , 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, increased 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](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  $\geq 75\%$  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>.

# 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  $\leq 1$  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<sub>3</sub> 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<sup>2</sup> intravenously
- Subsequent doses:
  - 600 mg/m<sup>2</sup> intravenously every 3 weeks, or
  - 400 mg/m<sup>2</sup> 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 <i>[see <a href="#">Warnings and Precautions (5.1)</a>]</i>	Grade 2	<ul style="list-style-type: none"> <li>• Interrupt the infusion until Grade <math>\leq 1</math>, then resume at a reduced infusion rate for the remaining infusion</li> <li>• Premedicate and administer the next infusion per the infusion rates as described in the full Prescribing Information</li> </ul>
	Grade 3 <sup>†</sup> 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).

<sup>†</sup>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<sub>3</sub>, 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 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 package:

- Carton of one 100 mg single-dose vial (NDC 0469-3425-10)

## Helpful links:

<b>VYLOY full Prescribing Information</b>	<a href="https://www.astellas.com/us/system/files/vyloy_pi.pdf">https://www.astellas.com/us/system/files/vyloy_pi.pdf</a>
<b>VYLOY Patient Website</b>	<a href="https://www.vyloy.com">https://www.vyloy.com</a>
<b>Patient Education Resources</b>	<a href="https://www.vyloy.com/resources">https://www.vyloy.com/resources</a>
<b>VYLOY Support Solutions<sup>SM</sup> Website</b>	<a href="https://vyloysupportsolutions.com">https://vyloysupportsolutions.com</a>
<b>VYLOY HCP Website</b>	<a href="https://www.vyloyhcp.com">https://www.vyloyhcp.com</a>
<b>HCP Support Materials</b>	<a href="https://www.vyloyhcp.com/access-and-resources">https://www.vyloyhcp.com/access-and-resources</a>

HCP, healthcare provider; NDC, National Drug Code.

Please [click here](#) for Important Safety Information and [click here](#) for full Prescribing Information.

## 2. Oracle Health Instructions

Existing PowerPlans may be used as a foundation for the new PowerPlan.  
Consider modifying an existing PowerPlan as a starting template

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### Step 1: Finding an existing PowerPlan to modify:

1. Open DCP tools
2. Select the PowerPlan tool in the Order Management section
3. Search for an existing order set by clicking Task > Open Plan
4. Enter the search terms "gastric," "gastroesophageal junction," or "GEJ" to find existing plans to optimize.  
Double-click on the plan to display its contents. *(Note: If no existing order sets are available, a new plan needs to be created, click Tasks > New Plan and define all clinical subcategories and select orderable items as desired)*

Note: The existing PowerPlan will serve as a template for the new VYLOY (zolbetuximab-clzb) PowerPlan only. If the original PowerPlan used to create or optimize the new VYLOY PowerPlan includes VYLOY, confirm it is retired or removed from the EHR production system according to the customer's EHR governing principles.

### Step 2: Modifying the PowerPlan to include VYLOY:

1. Update the display description
  - **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**
2. Update the description
  - **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**
3. In the **reference text field**, enter this text
  - VYLOY Prescribing Information  
See URL for additional VYLOY dosing and administration information: [https://www.astellas.com/us/system/files/vyloy\\_pi.pdf](https://www.astellas.com/us/system/files/vyloy_pi.pdf)
4. Click OK
5. In the evidence text field, add any link to an evidence-based resource or VYLOY resource as desired
6. Click on the Treatment Regimen section to update the **Treatment Regimen** and the **Treatment Calendar**

Please [click here](#) for Important Safety Information and [click here](#) for full Prescribing Information.



## 2. Oracle Health Instructions (cont'd)

### Step 2: Modifying the PowerPlan to include VYLOY: (cont'd)

7. Select the Medications Category. Enter VYLOY (zolbetuximab-clzb) in the lower right-hand panel in the Start Search field. Click the right arrow to move VYLOY to the Current List box and click Add. Edit the product details for all VYLOY medication options

- **VYLOY first dose: 800 mg/m<sup>2</sup>**
  - Complete the VYLOY medication details (800 mg/m<sup>2</sup> 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
  - For patient selection, prior to administration and premedication details, dose modifications for adverse reactions, preparation, administration, and infusion rate recommendations for VYLOY, refer to [https://www.astellas.com/us/system/files/vyloy\\_pi.pdf](https://www.astellas.com/us/system/files/vyloy_pi.pdf)
  - Infusion rates
    - Initial infusion rate (first 30-60 minutes): 100 mg/m<sup>2</sup>/hr\*
    - Subsequent infusion rate: 200-265 mg/m<sup>2</sup>/hr\*
- **VYLOY subsequent dose (option 1): 400 mg/m<sup>2</sup> intravenously every 2 weeks**
  - Complete the VYLOY medication details (400 mg/m<sup>2</sup> 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
  - For patient selection, prior to administration and premedication details, dose modifications for adverse reactions, preparation, administration, and infusion rate recommendations for VYLOY, refer to [https://www.astellas.com/us/system/files/vyloy\\_pi.pdf](https://www.astellas.com/us/system/files/vyloy_pi.pdf)
  - Infusion rates
    - Initial infusion rate (first 30-60 minutes): 50 mg/m<sup>2</sup>/hr\*
    - Subsequent infusion rate: 100-200 mg/m<sup>2</sup>/hr\*
- **VYLOY subsequent dose (option 2): 600 mg/m<sup>2</sup> intravenously every 3 weeks**
  - Complete the VYLOY medication details (600 mg/m<sup>2</sup> 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
  - For patient selection, prior to administration and premedication details, dose modifications for adverse reactions, preparation, administration, and infusion rate recommendations for VYLOY, refer to [https://www.astellas.com/us/system/files/vyloy\\_pi.pdf](https://www.astellas.com/us/system/files/vyloy_pi.pdf)
  - Infusion rates
    - Initial infusion rate (first 30-60 minutes): 75 mg/m<sup>2</sup>/hr\*
    - Subsequent infusion rate: 150-265 mg/m<sup>2</sup>/hr\*

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

Please [click here](#) for Important Safety Information and [click here](#) for full Prescribing Information.

## 2. Oracle Health Instructions (cont'd)

### Step 2: Modifying the PowerPlan to include VYLOY: (cont'd)

8. In the **Treatment Conditions** (alternatively, consider **Monitoring and Hold Parameters**), enter the following information:

#### Recommended dosing

- Administer VYLOY (zolbetuximab-clzb) in combination with fluoropyrimidine- and platinum-containing chemotherapy as follows:
  - First dose: 800 mg/m<sup>2</sup> intravenously
  - Subsequent doses:
    - 600 mg/m<sup>2</sup> intravenously every 3 weeks, or
    - 400 mg/m<sup>2</sup> 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 <i>[see Warnings and Precautions (5.1)].</i>	Grade 2	<ul style="list-style-type: none"> <li>• Interrupt the infusion until Grade <math>\leq 1</math>, then resume at a reduced infusion rate for the remaining infusion</li> <li>• Premedicate and administer the next infusion per the infusion rates as described in the full Prescribing Information</li> </ul>
	Grade 3 <sup>†</sup> or 4 or anaphylaxis	Immediately stop the infusion and permanently discontinue.

\*Toxicity was graded per NCI-CTCAE v5.0.

<sup>†</sup>Follow Grade 2 management for Grade 3 infusion-related nausea and vomiting.

Table 2: Infusion rates recommended for each VYLOY infusion

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

<sup>‡</sup>In the absence of adverse reactions after 30 to 60 minutes, the infusion rate can be increased to the subsequent infusion rate as tolerated.

Please [click here](#) for Important Safety Information and [click here](#) for full Prescribing Information.

## 2. Oracle Health Instructions (cont'd)

### Step 2: Modifying the PowerPlan to include VYLOY: (cont'd)

9. Once the regimen has been selected, update the Treatment Calendar
  - **First dose:**
    - 800 mg/m<sup>2</sup> intravenously
  - **Subsequent doses:**
    - 600 mg/m<sup>2</sup> intravenously every 3 weeks
    - OR**
    - 400 mg/m<sup>2</sup> intravenously every 2 weeks
  - Continue treatment until disease progression or unacceptable toxicity
10. In the **Important Safety Information** section, enter the following information:
  - See section 5 of the VYLOY (zolbetuximab-clzb) Prescribing Information for Important Safety Information (Hypersensitivity reactions, including anaphylaxis reactions, and infusion related reactions, severe nausea and vomiting): [https://www.astellas.com/us/system/files/vyloy\\_pi.pdf](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](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](https://www.astellas.com/us/system/files/vyloy_pi.pdf)
11. In the **VYLOY Premedication** section, enter 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<sub>3</sub> 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](https://www.astellas.com/us/system/files/vyloy_pi.pdf)
  - VYLOY may cause severe nausea and vomiting. Please refer to nausea and vomiting guidelines.
12. Click Task > Save Plan
13. Validate the newly optimized order set
14. Release to production environment 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 it 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; 2024.



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