NOW AVAILABLE

300 mg vial size now available for VYLOY® (zolbetuximab-clzb)[1]

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

Astellas Pharma US, Inc. is pleased to announce the approval of a

300 mg vial size (NDC: 0469-4425-30)

for VYLOY in addition to its current 100 mg vial size (NDC: 0469-3425-10).[1] This new 300 mg vial provides an additional size to use when preparing VYLOY while maintaining the same price per mg as the 100 mg vial.

NDC, National Drug Code.

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.

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 ≤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 click here for full Prescribing Information.

VYLOY can be administered every 2 or 3 weeks aligning with selected chemotherapy dosing schedule[1]

Recommended duration of treatment is until disease progression or unacceptable toxicity

VYLOY dosing[1]*	VYLOY administration[1]
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 BSA Recommended VYLOY dosage for each patient is based on body surface area	**If VYLOY and chemotherapy† are administered on the same day, VYLOY must be administered first.**

Prior to administration[1]

If a patient is experiencing nausea and/or vomiting, symptoms should be resolved to Grade ≤1 before the first infusion.

Premedication[1]

Prior to each VYLOY infusion, premedicate patients with a combination of antiemetics (eg, NK-1 receptor blockers and/or 5-HT3 receptor blockers, as well as other drugs as indicated) for the prevention of nausea and vomiting.

Please see VYLOY full Prescribing Information for additional information regarding infusion rates and dosage modifications

5-HT3, 5-hydroxytryptamine; **NK-1,** neurokinin-1.

*Administer VYLOY in combination with fluoropyrimidine- and platinum-containing chemotherapy.[1]
†Fluoropyrimidine- and platinum-containing chemotherapy.[1]

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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.

VYLOY is available through a network of specialty pharmacies and distributors

Specialty distributors

Self-dispensing physicians and practices with their own pharmacies will be able to order VYLOY through the network of specialty distributors.

ASD Healthcare
P: (800) 746-6273
F: (800) 547-9413
www.asdhealthcare.com

Besse Medical
P: (800) 543-2111
F: (800) 543-8695
www.besse.com

Cardinal Health Specialty Distribution
P: (855) 855-0708
F: (614) 553-6301
specialtyonline.cardinalhealth.com

Cesar Castillo, Inc. (Puerto Rico)
P: (787) 641-5082
F: (787) 999-1614
cesarcastillo.com

McKesson Plasma and Biologics, LLC
P: (877) 625-2566
F: (888) 752-7626
www.mckesson.com

McKesson Specialty Health
P: (800) 482-6700
F: (800) 289-9285
www.mckessonspecialtyhealth.com

Oncology Supply
P: (800) 633-7555
F: (800) 248-8205
www.oncologysupply.com

Specialty pharmacies

Physicians who choose to access VYLOY through specialty pharmacies will be able to do so by contacting 1 of the specialty pharmacies below.

Biologics, Inc.
P: (800) 850-4306
F: (800) 823-4506
www.biologicsinc.com

Onco360 Pharmacy
P: (877) 662-6633
F: (877) 662-6355
www.onco360.com

	NOW AVAILABLE **300 mg single-dose vial**	**100 mg single-dose vial**
NDC[1]	0469-4425-30	0469-3425-10
How supplied[1]	White to off-white lyophilized powder for reconstitution in a carton containing one vial	White to off-white lyophilized powder for reconstitution in a carton containing one vial
Bar code[2] (unit carton)	3 04694 42530 0	3 04693 42510 3
Bar code[2] (shipping case)	(01)60304694425302	(01)60304693425105

Coding and billing*

Until a specific permanent Healthcare Common Procedure Coding System (HCPCS) code is assigned, bill for VYLOY using unspecified HCPCS codes. These include: J3490, J3590, J9999, and C9399 (the latter for Medicare Hospital Outpatient claims). Additional information needed may vary by payer and may include the drug name and generic name, total dosage administered, method of administration, and the NDC. Providers should confirm this information by payer.

The information contained in this resource is accurate as of March 26, 2025. The list of participating specialty pharmacies and specialty distributors may change without notice. Visit VYLOYSupportSolutions.com for the most current list of participating specialty pharmacies and specialty distributors.

*Each healthcare provider is responsible for determining the appropriate codes, coverage, and payment for individual patients. Astellas does not guarantee third party coverage, payment, or reimbursement for denied claims. Insurance coverage, coding, claims filing, and reimbursement vary by setting of care as well as by payer type. Healthcare providers should always verify coverage prior to initiating therapy and determine the appropriate codes on a case-by-case basis.

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 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.

References: 1. VYLOY. Package insert. Northbrook, IL: Astellas Pharma US, Inc; 2025. **2.** Astellas. VYLOY. Data on File.

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