

Your VYLOY Treatment Guide

VYLOY is a targeted treatment used in combination with chemotherapy as a first therapy for people with advanced* cancer of the stomach or the area where the esophagus joins the stomach (GEJ) that is HER2-negative and claudin 18.2 positive



Live in the positive

+CONNECTIONS +POSSIBILITIES +MOMENTS

*Cancer that cannot be removed with surgery or has spread to other parts of the body.
GEJ=gastroesophageal junction.

What is VYLOY?

VYLOY is a prescription medicine used to treat adults with cancer of the stomach (gastric cancer) or cancer located where the esophagus joins the stomach (gastroesophageal junction cancer). VYLOY is used in combination with chemotherapy that contains fluoropyrimidine and platinum as the first treatment when your gastric or gastroesophageal junction cancer:

- cannot be removed with surgery or has spread to other parts of the body,
- is HER2-negative, **and**
- your tumor tests positive for "claudin (CLDN)18.2."

It is not known if VYLOY is safe and effective in children.

SELECT SAFETY INFORMATION

Before receiving VYLOY, tell your healthcare provider about all of your medical conditions, including if you:

- have nausea or vomiting.
- are pregnant or plan to become pregnant. It is not known if VYLOY will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if VYLOY passes into your breast milk. Do not breastfeed during treatment with VYLOY and for 8 months after the last dose.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

VYLOY[®]
zolbetuximab-clzb
for injection 100mg vial

Please see [Important Safety Information](#) on page 18, and read the [Patient Information](#).



Getting started on a positive note

It's natural to have questions when you or a loved one is about to start a cancer treatment. This guide can help provide important information about your disease and treatment with VYLOY.

This guide should not replace the advice of your healthcare team. Remember to talk to your doctor any time you have questions about advanced stomach or GEJ cancer and your treatment with VYLOY.

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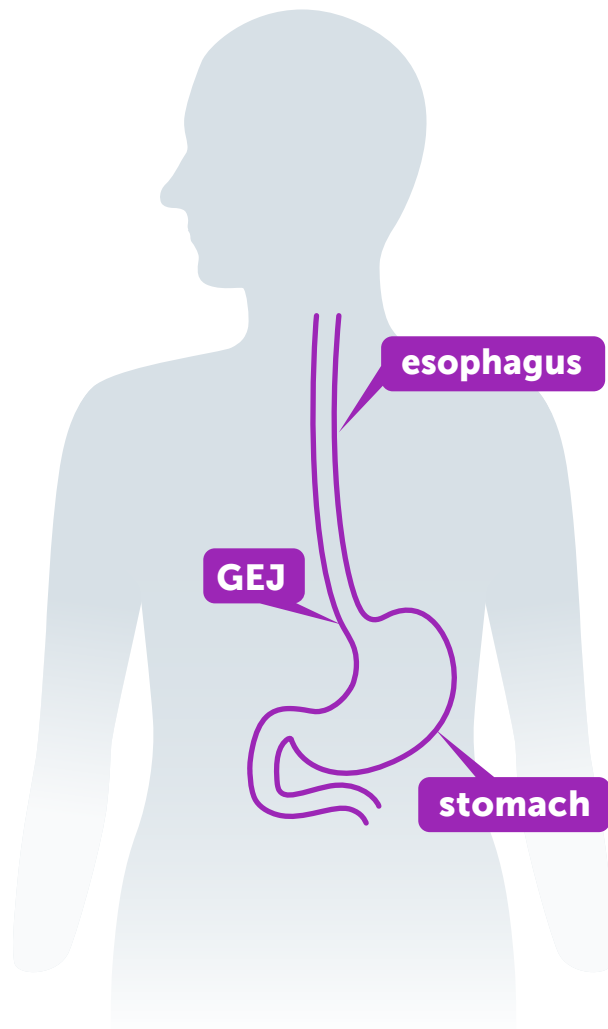
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Please refer to the glossary for the definitions of underlined words in the guide.



A diagnosis of advanced stomach or GEJ cancer can leave you feeling overwhelmed. You should remember you are not alone in dealing with this disease.

Stomach cancer is also known as [gastric](#) cancer. It forms in the cells lining the stomach. Cancer can also form in the [gastroesophageal junction \(GEJ\)](#). The GEJ is the place where the [esophagus](#) connects to the stomach.





Stomach and GEJ cancer have symptoms that can be similar to other conditions, **making them difficult to diagnose.**

Most cases of stomach and GEJ cancer in the United States are not caught until they are in the advanced stages.

This means the cancer is either:

Locally advanced unresectable

It has spread from where it started to nearby tissues or lymph nodes and is unable to be removed with surgery

-or-

Metastatic

It has spread from where it started to other places in the body

It was estimated that there would be approximately 26,500* new cases of stomach cancer in the United States in 2023.

*The Surveillance, Epidemiology, and End Results Program of the National Cancer Institute does not have a separate classification for GEJ cancer apart from esophageal cancer; therefore, true GEJ cancer projections are unknown. This makes it difficult to project an estimated number of new cases of GEJ cancer.



Each of us is unique and so is each case of advanced stomach/GEJ cancer.

One of the things that can differentiate your case of advanced stomach/GEJ cancer is the presence or absence of certain biomarkers.

A biomarker is a molecule that is found in the body. In some cases of cancer, it can be a protein found on the surface of a tumor.

Biomarker testing is used to gather more information about the specific type of cancer. These results help doctors understand the different features of the cancer.

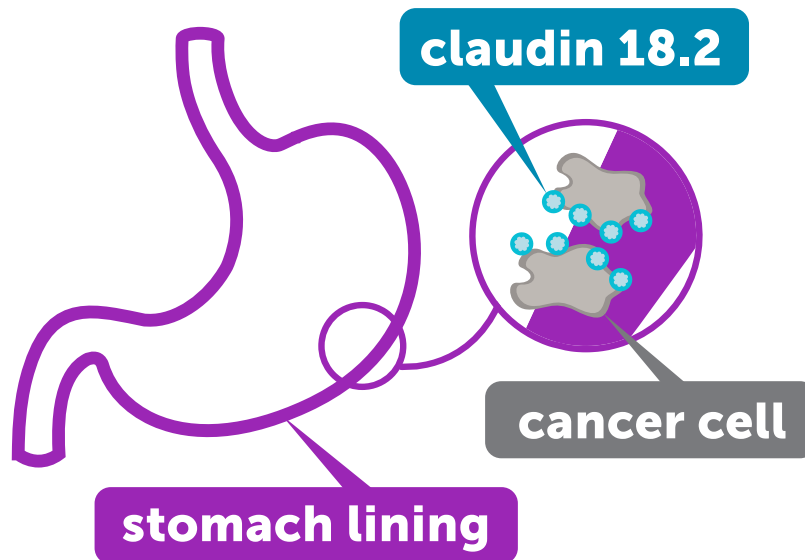
If your cancer tests positive for a specific biomarker, this information can help you and your doctor choose a treatment that may be more appropriate for you.

[Targeted therapy](#) is a type of treatment that uses medicines to target specific molecules on cancer cells. Targeted therapies work in different ways to treat cancer. Targeted therapies, while specific, can also affect other tissues in the body.

UNDERSTANDING CLAUDIN 18.2

The protein [claudin 18.2](#) is a biomarker that has been estimated to be present in **more than a third** of advanced stomach/GEJ cancer patients.

It is **one of the most common biomarkers in stomach and GEJ cancers**. Claudin 18.2 is typically found in the stomach lining. When cancer develops, claudin 18.2 may become more exposed at the surface of the cancer cell.



If you test positive for a biomarker like claudin 18.2, it could mean there is a targeted therapy that may be able to help treat your cancer.

VYLOY is the first FDA-approved treatment that targets the biomarker claudin 18.2 in advanced stomach/GEJ cancer.

VYLOY is a prescription medicine used to treat adults with cancer of the stomach (gastric cancer) or cancer located where the esophagus joins the stomach (gastroesophageal junction cancer). VYLOY is used in combination with chemotherapy that contains fluoropyrimidine and platinum as the first treatment when your gastric or gastroesophageal junction cancer:

- **Cannot be removed** with surgery or **has spread to other parts** of the body,
- Is [HER2](#)-negative, **and**
- Your tumor tests positive for [claudin](#) (CLDN)18.2.

It is not known if VYLOY is safe and effective in children.

VYLOY was tested in two separate studies involving over 1000 patients.

SELECT SAFETY INFORMATION

What are the possible side effects of VYLOY?

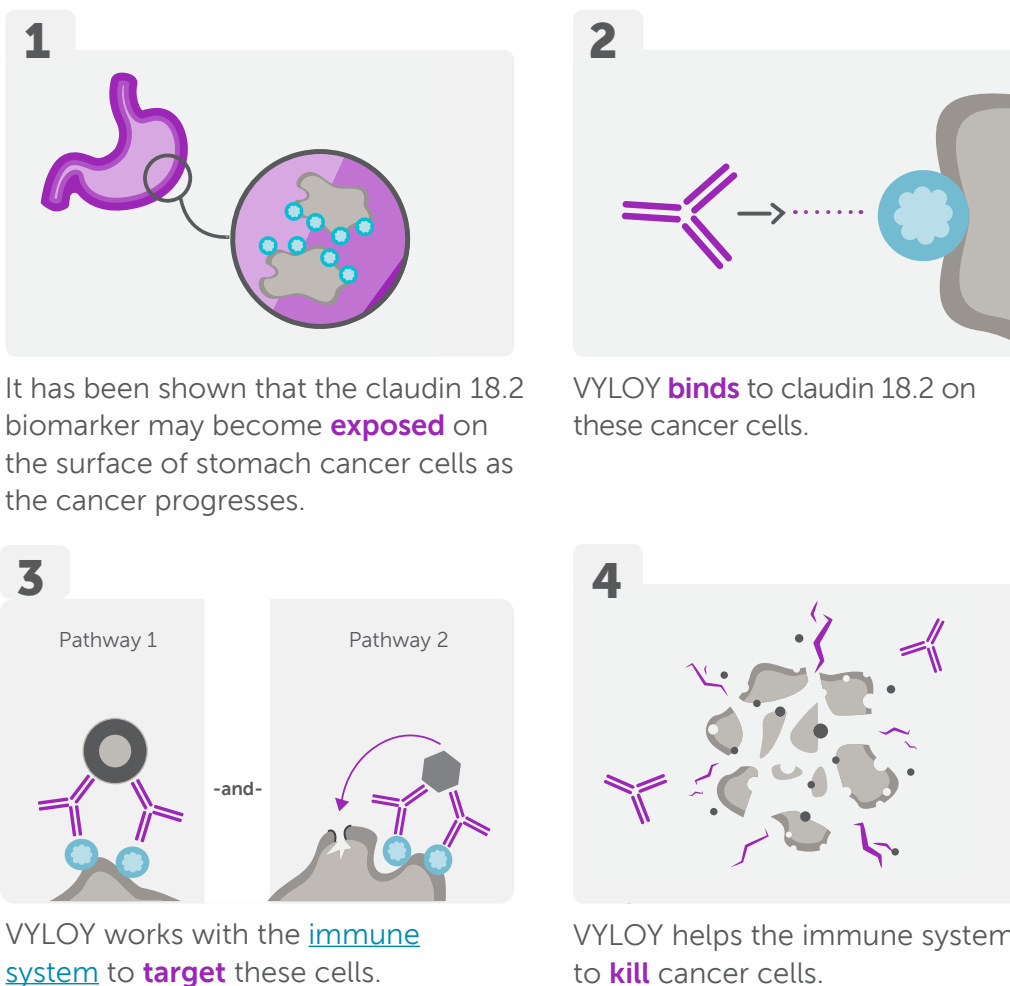
VYLOY may cause serious side effects, including:

- **Allergic reactions, including anaphylaxis and infusion-related reactions.** Allergic reactions are common during treatment with VYLOY and can sometimes be serious. Serious allergic reactions can happen during or after your VYLOY infusion, including life-threatening allergic reactions and serious infusion-related reactions that may lead to death. Your healthcare provider will monitor you during your infusion and for 2 hours after or longer if needed. Tell your healthcare provider or get emergency medical help right away if you get any of the following symptoms of a serious allergic reaction during or after your infusion of VYLOY:
 - itchy, raised bumps on the skin (hives)
 - coughing that does not go away
 - nausea or vomiting
 - stomach (abdominal) pain
 - increased saliva
 - breathing problems such as wheezing
 - throat tightness or change in voice
 - fever
 - chest discomfort
 - chills or shaking
 - back pain
- **Severe nausea and vomiting.** Nausea and vomiting are common during treatment with VYLOY and can sometimes be severe. Nausea and vomiting happened more often during the first treatment cycle. Before you receive each VYLOY infusion, your healthcare provider will give you medicines to help prevent nausea and vomiting. Tell your healthcare provider right away if nausea or vomiting does not go away or gets worse.

HOW VYLOY IS THOUGHT TO WORK

VYLOY is different than chemotherapy. It is a treatment that targets the biomarker claudin 18.2 on stomach cancer cells.

This is how VYLOY was shown to work in lab studies:



stomach



claudin 18.2



VYLOY



immune cell



cancer cell



immune protein

You will receive VYLOY:

- **As an intravenous infusion** (through your vein)
- Followed by **chemotherapy** that contains fluoropyrimidine and platinum
- **Every 2 or 3 weeks**, depending on the chemotherapy chosen by your healthcare team
- Your first VYLOY infusion will last a **minimum of 3.5 hours**. Subsequent VYLOY infusions may take less time



First VYLOY infusion



Subsequent VYLOY infusions

You will be monitored during and after your infusion to see how your body reacts to treatment. Before you receive your VYLOY infusion or during your treatment, your healthcare provider will give you medicine to help prevent or treat nausea and vomiting.

Your healthcare provider will decide how many treatments you need.

SELECT SAFETY INFORMATION

The most common side effects of VYLOY include:

- tiredness
- decreased appetite
- diarrhea
- tingling or numbness of the arms or legs
- stomach (abdominal) pain
- constipation
- decreased weight
- fever
- decreased white blood cells, red blood cells and platelets
- decreased protein (albumin) in the blood
- changes in kidney function tests
- changes in blood sugar (glucose)
- changes in liver functions tests
- changes in body salts (electrolytes) in your blood



Tips for infusion day

Starting a cancer treatment can create anxiety in some people. Being prepared can make infusion day a better experience. Here are some tips that may be helpful:

- **Wear comfortable clothing** (nothing tight or restrictive)
- **Bring a blanket** or throw to stay warm
- **Ask about bringing a snack** to your infusion
- **Bring a book**, magazine, or game to pass the time
- **Bring a friend or relative** for company
- **Try self-guided meditation** or breathing exercises

**Keep track of how you feel during and after your infusion.
Share questions and concerns with your healthcare team.**

SELECT SAFETY INFORMATION

Your healthcare provider may slow the rate of your infusion, temporarily stop, or completely stop treatment with VYLOY if you have certain side effects. These are not all of the possible side effects of VYLOY. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

What are the possible side effects of VYLOY?

VYLOY may cause serious side effects, including:

- **Allergic reactions, including anaphylaxis and infusion-related reactions.** Allergic reactions are common during treatment with VYLOY and can sometimes be serious. Serious allergic reactions can happen during or after your VYLOY infusion, including life-threatening allergic reactions and serious infusion-related reactions that may lead to death. Your healthcare provider will monitor you during your infusion and for 2 hours after or longer if needed. Tell your healthcare provider or get emergency medical help right away if you get any of the following symptoms of a serious allergic reaction during or after your infusion of VYLOY:
 - itchy, raised bumps on the skin (hives)
 - coughing that does not go away
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 - throat tightness or change in voice
 - fever
 - chest discomfort
 - chills or shaking
 - back pain

Trial 1 enrolled 565 patients with advanced* stomach or GEJ cancer whose tumors were HER2-negative and claudin 18.2 positive. It compared 283 patients who received VYLOY with mFOLFOX6, a type of chemotherapy, to 282 patients who received mFOLFOX6 alone.

During the trial _____

VYLOY + chemotherapy helped more people live without their cancer getting worse versus chemotherapy alone.

Median progression-free survival time



Median progression-free survival is the time in the study that half the patients lived without their cancer getting worse.

*Cancer that cannot be removed with surgery or has spread to other parts of the body.

During the trial _____

VYLOY + chemotherapy helped more people live longer versus chemotherapy alone.

Median overall survival time was 18.2 months with VYLOY + chemotherapy vs 15.5 months for chemotherapy alone

Median overall survival is the time in the study that half the patients were still alive.

SELECT SAFETY INFORMATION

What are the possible side effects of VYLOY?

VYLOY may cause serious side effects, including:

- **Severe nausea and vomiting.** Nausea and vomiting are common during treatment with VYLOY and can sometimes be severe. Nausea and vomiting happened more often during the first treatment cycle. Before you receive each VYLOY infusion, your healthcare provider will give you medicines to help prevent nausea and vomiting. Tell your healthcare provider right away if nausea or vomiting does not go away or gets worse.

After the study ended

Some patients being treated in Trial 1 were assessed at 1 and 2 years. These results were not used to determine how well VYLOY performed and they only reflect the experience of these patients. Your experience may be different.

Progression-free survival is the length of time from the start of treatment that a patient lives with the cancer without their disease getting worse.

At 1 year **49% of patients** on VYLOY + chemotherapy were progression-free
35% of patients on chemotherapy alone were progression-free

At 2 years **24% of patients** on VYLOY + chemotherapy were progression-free
15% of patients on chemotherapy alone were progression-free

Overall survival is the length of time from the start of treatment that a patient is still alive.

At 1 year **68% of patients** on VYLOY + chemotherapy were still alive
60% of patients on chemotherapy alone were still alive

At 2 years **39% of patients** on VYLOY + chemotherapy were still alive
28% of patients on chemotherapy alone were still alive

SELECT SAFETY INFORMATION

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- stomach (abdominal) pain
- constipation
- decreased weight
- fever
- decreased white blood cells, red blood cells and platelets
- decreased protein (albumin) in the blood
- changes in kidney function tests
- changes in blood sugar (glucose)
- changes in liver functions tests
- changes in body salts (electrolytes) in your blood

Trial 2 enrolled **507 patients** with advanced* stomach or GEJ cancer whose tumors were HER2-negative and claudin 18.2 positive. It compared **254 patients** who received VYLOY with [CAPOX](#), a type of chemotherapy, to **253 patients** who received CAPOX alone.

During the trial _____

VYLOY + chemotherapy helped more people live without their cancer getting worse versus chemotherapy alone.

Median progression-free survival time



Median progression-free survival is the time in the study that half the patients lived without their cancer getting worse.

*Cancer that cannot be removed with surgery or has spread to other parts of the body.

During the trial _____

VYLOY + chemotherapy helped more people live longer versus chemotherapy alone.

Median overall survival time was **14.4 months** with VYLOY + chemotherapy vs **12.2 months** for chemotherapy alone

Median overall survival is the time in the study that half the patients were still alive.

SELECT SAFETY INFORMATION

Your healthcare provider may slow the rate of your infusion, temporarily stop, or completely stop treatment with VYLOY if you have certain side effects. These are not all of the possible side effects of VYLOY. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

After the study ended

Some patients being treated in Trial 2 were assessed at 1 and 2 years. These results were not used to determine how well VYLOY performed and they only reflect the experience of these patients. Your experience may be different.

Progression-free survival is the length of time from the start of treatment that a patient lives with the cancer without their disease getting worse.

At 1 year **35% of patients** on VYLOY + chemotherapy were progression-free
19% of patients on chemotherapy alone were progression-free

At 2 years **14% of patients** on VYLOY + chemotherapy were progression-free
7% of patients on chemotherapy alone were progression-free

Overall survival is the length of time from the start of treatment that a patient is still alive.

At 1 year **58% of patients** on VYLOY + chemotherapy were still alive
51% of patients on chemotherapy alone were still alive

At 2 years **29% of patients** on VYLOY + chemotherapy were still alive
17% of patients on chemotherapy alone were still alive

SELECT SAFETY INFORMATION

What are the possible side effects of VYLOY?

VYLOY may cause serious side effects, including:

- **Allergic reactions, including anaphylaxis and infusion-related reactions.** Allergic reactions are common during treatment with VYLOY and can sometimes be serious. Serious allergic reactions can happen during or after your VYLOY infusion, including life-threatening allergic reactions and serious infusion-related reactions that may lead to death. Your healthcare provider will monitor you during your infusion and for 2 hours after or longer if needed. Tell your healthcare provider or get emergency medical help right away if you get any of the following symptoms of a serious allergic reaction during or after your infusion of VYLOY:
 - itchy, raised bumps on the skin (hives)
 - coughing that does not go away
 - nausea or vomiting
 - stomach (abdominal) pain
 - increased saliva
 - breathing problems such as wheezing
 - throat tightness or change in voice
 - fever
 - chest discomfort
 - chills or shaking
 - back pain

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- changes in kidney function tests
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- changes in body salts (electrolytes) in your blood

Your healthcare provider may slow the rate of your infusion, temporarily stop, or completely stop treatment with VYLOY if you have certain side effects. These are not all of the possible side effects of VYLOY. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.



Knowing what to expect can help you be prepared

If VYLOY and chemotherapy are given on the same day, VYLOY will be given first. Your first VYLOY infusion will last a minimum of 3.5 hours. Subsequent VYLOY infusions may take less time. Depending on the chemotherapy selected by your doctor, your treatment may take another 2-3 hours.

- **Nausea and vomiting** are common side effects of VYLOY, and can sometimes be severe. **They occur most often during the first cycle**
- Prior to your treatment with VYLOY, **your healthcare provider will give you medicine to help prevent nausea and vomiting**

If you experience nausea, vomiting, or certain side effects, your healthcare provider may slow the rate of your infusion or stop your treatment with VYLOY, either temporarily or permanently.



Keep your healthcare team informed moving forward

Speak up if you experience any new side effects, ones that do not go away, or if they get worse.

If you have trouble tolerating treatment, your treatment may be adjusted accordingly.



Here are some tips that have helped others:

- Keep a **treatment journal** to share with your team
- Stay **hydrated**. Drink plenty of water and other fluids
- Work with your healthcare team to make a plan for **good nutrition**
- Try to **focus on the positive**. Surround yourself with people and things you love
- Take a **walk or sit outside** to get some fresh air

Before receiving VYLOY, tell your healthcare provider about all of your medical conditions, including if you:

- have nausea or vomiting.
- are pregnant or plan to become pregnant. It is not known if VYLOY will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if VYLOY passes into your breast milk. Do not breastfeed during treatment with VYLOY and for 8 months after the last dose.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

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- changes in liver functions tests
- changes in body salts (electrolytes) in your blood

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Support when you need it most

Learning you have cancer isn't easy. It's a moment that hits hard and can feel overwhelming to you and those who care about you. **Remember there's support** available that can help you find the positive.

Advocacy groups play a crucial role in helping patients and families affected by stomach/GEJ cancer. They are a great resource for information and can connect you to support groups if you want to talk.



It takes a team to take on stomach/GEJ cancer. These organizations may help.



Debbie's Dream Foundation
debbiesdream.org | (855) 475-1200



Gastric Cancer Foundation
gastriccancer.org



GI Cancers Alliance
gicancersalliance.org | (646) 598-2001



Hope For Stomach Cancer
stocan.org | (424) 239-9943

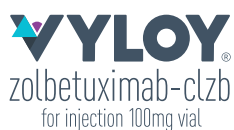


No Stomach For Cancer
nostomachforcancer.org | (608) 692-5141



Patient Empowerment Network
powerfulpatients.org

Astellas is not affiliated with and does not endorse any of the listed organizations. The information provided by Astellas is for informational purposes only and is not meant to replace the advice of a healthcare professional.



Please see [Important Safety Information](#) on page 18, and read the [Patient Information](#).



VYLOY Support Solutions™ offers access and reimbursement support to help patients who have been prescribed VYLOY. We are here to answer questions regarding your insurance coverage and can provide you with information about patient support programs that may be available to you.



Financial Assistance

VYLOY Support Solutions can help with potential affordability challenges, whether you have commercial prescription insurance, are uninsured, or have government insurance (eg, Medicare, Medicaid).

- **VYLOY Copay Assistance Program^a**

If you have private commercial insurance and are not insured by any federal or state healthcare program, you may be eligible for the VYLOY Copay Assistance Program, which allows eligible patients to pay **as little as \$5 per dose**. The Program can help save up to a maximum of \$25,000 per calendar year.^a

- **Astellas Patient Assistance Program**

If you are uninsured or have insurance that excludes coverage for VYLOY, you may be eligible for the Astellas Patient Assistance Program, which provides VYLOY **at no cost**.^b

- **Financial Assistance Information**

If you need additional financial assistance, VYLOY Support Solutions can provide information about other sources of support that may be able to help.

^aBy enrolling in the VYLOY Copay Assistance Program (“Program”), the patient acknowledges that they currently meet the eligibility criteria and will comply with the following terms and conditions: The Program is for eligible patients with commercial prescription insurance for VYLOY[®] (zolbetuximab) and is good for use only with a valid prescription for VYLOY. The Program has an annual maximum copay assistance limit of \$25,000 per calendar year. After the annual maximum on copay assistance is reached, patient will be responsible for the remaining monthly out-of-pocket costs for VYLOY. **The Program is not valid for patients who are insured by any state or federal government program, including, but not limited to, Medicaid, Medicare, Medigap, Department of Defense (DoD), Veterans Affairs (VA), TRICARE, Puerto Rico Government Insurance, or any state patient or pharmaceutical assistance program.** Patients who move from commercial insurance to federal or state prescription health insurance will no longer be eligible, and agree to notify the Program of any such change. This offer is not valid for cash paying patients. Patients agree not to seek reimbursement from any health insurance or third party for all or any part of the benefit received by the patient through the Program. This offer is not conditioned on any past, present, or future purchase of VYLOY. This offer is not transferrable, has no cash value, and cannot be combined with any other offer, free trial, prescription savings card, or discount. The full value of the Program benefits is intended to pass entirely to the eligible patient. The benefit available under this Program is valid only for the patient’s out-of-pocket medication costs for VYLOY. The benefit is not valid for any other out-of-pocket costs such as medication administration charges or other healthcare provider services. No other individual or entity (including, without limitation, third party payers, pharmacy benefit managers, or the agents of either) is entitled to receive any benefit, discount, or other amount in connection with this Program. **This offer is not health insurance** and is only valid for patients in the 50 United States, Washington DC, and Puerto Rico. This Program is void where prohibited by law. No membership fees. Certain rules and restrictions apply. Astellas reserves the right to revoke, rescind, or amend this offer without notice for any reason (including to ensure that the offer is utilized solely for the patient’s benefit).

^bSubject to eligibility. Program terms and conditions apply. Void where prohibited by law.

Continue to page 23 to learn about additional support services available to patients and caregivers.

Patient / Caregiver Support

Patient Connect

This additional support helps connect you and your caregiver to resources that can provide emotional, logistical, and informational support to assist in managing daily life while being treated with VYLOY.

When you or your caregiver calls VYLOY Support Solutions, a trained representative will assess your specific needs and customize a search of various independent local and national organizations^a that may provide the support and resources requested.

Get Started

Ask your healthcare provider to enroll you in VYLOY Support Solutions. Once enrolled, you will have access to the full range of support.

Contact VYLOY Support Solutions to learn more



1-855-272-6609 | Monday–Friday 8:00 AM–8:00 PM ET



[VYLOYSupportSolutions.com](https://www.vyloymeds.com/support)

^aSupport is provided through third-party organizations that operate independently and are not controlled or endorsed by Astellas. Availability of support and eligibility requirements are determined by these organizations.

BIOMARKER

A biological molecule found in blood, other body fluids, or tissues that is a sign of a normal or abnormal process, or of a condition or disease

CAPOX

A chemotherapy combination regimen used to treat gastric/GEJ cancer. It consists of the drugs capecitabine and oxaliplatin

CLAUDIN 18.2

A protein usually found between the cells that line the stomach wall. It may be exposed on the surface of some stomach cancer cells

ESOPHAGUS

The muscular tube through which food passes from the throat to the stomach

mFOLFOX6

A chemotherapy combination regimen used to treat gastric/GEJ cancer. It consists of the drugs fluorouracil (5-FU), leucovorin calcium (folinic acid), and oxaliplatin

GASTRIC

Having to do with the stomach

GASTROESOPHAGEAL JUNCTION (GEJ)

The place where the esophagus connects to the stomach

HER2 (human epidermal growth factor receptor 2)

A protein involved in normal cell growth. It may be found in some types of cancers, and may cause the cancer to grow more quickly and spread to other parts of the body

IMMUNE SYSTEM

A network of cells, tissues, and organs that helps the body fight infections and other diseases

MEDIAN OVERALL SURVIVAL

The length of time from the start of treatment for a disease, such as cancer, that half of the patients in a group of patients diagnosed with the disease are still alive

MEDIAN PROGRESSION-FREE SURVIVAL

The length of time from the start of treatment for a disease, such as cancer, that half of the patients in a group of patients diagnosed with the disease live with the disease but it does not get worse

OVERALL SURVIVAL

The length of time from either the date of diagnosis or the start of treatment for a disease, such as cancer, that patients diagnosed with the disease are still alive

PROGRESSION-FREE SURVIVAL

The length of time from the start of treatment that a patient lives with the cancer without their disease getting worse

TARGETED THERAPY

A type of treatment that uses medicines to target specific molecules that cancer cells need to survive and spread. Targeted therapies work in different ways to treat cancer



Visit [VYLOY.com](https://www.vylo.com) to learn more

VYLOY[®]
zolbetuximab-clzb
for injection 100mg vial

Please see [Important Safety Information](#) on page 18,
and read the [Patient Information](#).



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is a trademark of Astellas Pharma US, Inc.