Pr VYLOY® zolbetuximab for injection

Patient Support Program
Patient Enrolment and Consent Form

Email: Vyloy@bayshore.ca | **Phone:** 1-844-553-2536 (1-844-553-CLDN) | **Fax:** 1-855-448-0512

All fields are mandatory unless otherwise indicated.

PATIENT INFORMATION

Name: First name | Middle name | Last name | **Date of birth:** DD/MM/YYYY | ☐ Female ☐ Male

Preferred contact: Street # | Street name | City | Province | Postal code

Preferred phone # | Alternate phone # | Email address

Best time to contact: ☐ Morning ☐ Afternoon ☐ Night

Language: ☐ English ☐ French ☐ Other: _____

Designate caregiver as primary contact? ☐ Yes ☐ No

Caregiver contact details Name: | Phone #:

Email address:

Consent to leave voicemail? ☐ Yes ☐ No

TREATING PHYSICIAN INFORMATION

Name: First name | Middle name | Last name | MD License #:

Practice address: Hospital/clinic name | Floor | Room #

Street # | Street name | City | Province | Postal code

Contact: Phone # | Fax # | Email address

Health Care Professional Certification Where Verbal Consent is Obtained (if applicable): I confirm that I have discussed the VYLOY Patient Support Program with my patient and have explained how personal information will be collected, used, and disclosed by the Program to my patient. I have obtained verbal consent from my patient to share their personal information in this form with the Program, and as needed to provide the Program's services.

Health Care Professional signature: ▶ _____ DD/MM/YYYY

Prescribing Physician Acknowledgement: I confirm that I am the prescribing physician and the prescription is an original prescription. I agree to be contacted by Bayshore Healthcare, its affiliates and partners in connection with this patient's care and/or enrolment in the Patient Support Program. I authorize Bayshore Healthcare as my designated agent for the purposes of forwarding this prescription, by fax or other mode of delivery, to the appropriately designated pharmacy. I agree to the disclosure of my personal information to Bayshore Healthcare and Astellas for Program reporting, evaluations, and other research or business purposes.

Physician signature: ▶ _____ DD/MM/YYYY

DIAGNOSIS AND CLINICAL INFORMATION

Patient status: ☐ Outpatient ☐ Hospitalized

Patient is ≥18 years of age: ☐ Yes ☐ No

Primary diagnosis: ☐ Gastric ☐ Gastroesophageal junction (GEJ)

CLDN 18.2-positive: ☐ Yes ☐ No ☐ Pending

Date of CLDN 18.2 testing: MM/YYYY

HER2-negative: ☐ Yes ☐ No ☐ Unknown

Date of HER2 testing: MM/YYYY

ECOG performance status: ☐ 0 ☐ 1

Is PD-L1 CPS score available? (*Optional)** ☐ No ☐ Yes Value: ☐ 0 ☐ ≤1 ☐ >1 ☐ >5 ☐ >10

Combination therapy confirmation: ☐ VYLOY + mFOLFOX6 ☐ VYLOY + CAPOX ☐ VYLOY + Other: _____

Confirming utilization of VYLOY in alignment with the approved indication† ☐ Yes ☐ No

* The information provided will be used for the collection of Real-World Data.
† VYLOY, in combination with fluoropyrimidine- and platinum-containing chemotherapy, is indicated for the first-line treatment of patients with locally advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-negative gastric or gastroesophageal junction (GEJ) adenocarcinoma whose tumours are Claudin (CLDN) 18.2 positive as determined by a validated test.

OFFICIAL PHARMACY PRESCRIPTION

Prescription: ☐ VYLOY (zolbetuximab)

Anticipated start date: DD/MM/YYYY

Authorization to start: ☐ Yes ☐ No

Body surface area: _____ m²

Initial dosing: ☐ 800 mg/m² VYLOY IV on day 1

Subsequent dosing: ☐ 600 mg/m² VYLOY IV q3w ☐ 400 mg/m² mg VYLOY IV q2w

Total number of cycles: _____

Infusion location: ☐ Bayshore private infusion clinic ☐ Hospital

Hospital Delivery address (if applicable): Street # | Street name

City | Province | Postal code

Other instructions:

Please note that a signature will be required at delivery.
Please refer to the Product Monograph for complete details on dosing and administration.

Prescriber signature: ▶ _____ DD/MM/YYYY

This prescription above is recognized as an original prescription and has been faxed only to be filled by the single regional pharmacy receiving it directly from the Program, if the patient chooses to opt for that service. The original of this prescription has been securely filed and will not be faxed elsewhere at another time.

ANTIEMETIC AND PRE-MEDICATION TREATMENT

Antiemetic treatment prescribed to patient: ☐ Yes ☐ No ☐ Treatment: _____

Pre-medication treatment prescribed to patient: ☐ Yes ☐ No ☐ Treatment: _____

NURSE, PHARMACIST, OR DRUG ACCESS NAVIGATOR INFORMATION

Name: First name | Last name | Email address | Phone # | Fax #

Preferred method of contact: ☐ Email ☐ Phone ☐ Fax

Please email/fax "post-infusion report" and "Medical clarification" to: ☐ Physician ☐ Nurse ☐ Pharmacist ☐ Drug Access Navigator

Special instructions:

Turn page over...

Patient Enrolment and Consent Form

The **VYLOY Patient Support Program** (the "**Program**") provides support services to Canadian patients that have been prescribed PrVYLOY® (zolbetuximab for injection) by a Canadian physician. The Program provides services in the following areas: reimbursement navigation, pharmacy dispensing and coordination, infusion services, and education services.

The Program is offered by Astellas Pharma Canada, Inc., its affiliates and agents ("Astellas") and is administered by Bayshore Healthcare ("Program Administrator"). If Bayshore Healthcare ceases to be the Program Administrator, Astellas may appoint a replacement, and I agree that my information may be transferred to and used by the replacement Program Administrator in the manner described on this form, to continue to provide me with support services.

I understand that my personal information, including the information that I provide by completing this Patient Enrolment and Consent Form, and information about my insurance, prescriptions, medical condition, and health ("**Personal Information**") will be collected, used, shared, and stored, as described on this form and in compliance with privacy laws. I authorize my health care providers and my health insurers to share my Personal Information with the Program Administrator for the purpose of my participation in the Program.

My Personal Information will be used by the Program Administrator to:

- Contact me and my caregiver to complete my enrolment in the Program and to provide the Program services.
- Communicate with my health insurer to determine if I am eligible for reimbursement.
- Communicate with my physician, pharmacist, and other health care providers when appropriate.
- Contact me and my caregiver to ask about my experience with the Program and conduct other research for the purposes of improving the services offered by Astellas.

My Personal Information may also be used to perform assessments of the Program and to provide reports to Astellas on the Program services and operations. I understand that my name will be masked/not included in any report that is shared with Astellas. These reports that contain my Personal Information (with my name masked) may be used for internal evaluations, Program auditing, product development, market research or real-world evidence purposes.

My Personal Information may also be collected, used and disclosed to health authorities, such as Health Canada, for adverse reaction reporting and fulfillment of other regulatory obligations of Astellas.

I understand that my Personal Information may be transferred and stored outside of Canada where it would become subject to laws that may differ from Canada regarding protection and personal information. Astellas implements appropriate measures to protect Personal Information when it is transferred outside of Canada.

My consent is voluntary, and I can withdraw my consent for the collection, use, and disclosure of my Personal Information, or request access to my Personal Information, by contacting the Program at Vyloy@bayshore.ca. Unless and until revoked, this consent is valid for the duration of the Program. I understand that if I withdraw consent for the collection, use, and disclosure of my Personal Information, I will no longer be able to receive support services or remain in the Program. My Personal Information may be retained after I leave the Program to meet applicable legal and regulatory requirements.

I acknowledge that Astellas may, without advance notice, change the scope of the services or the eligibility requirements for the Program, discontinue the Program or any of the services currently offered.

<u>Consent to Use Personal Information for Future Studies</u>

If indicated below, I authorize the Program Administrator to collect my personal information from me or my caregiver, or from my physician or other health care providers, on my use of PrVYLOY® (zolbetuximab for injection) and other products, my health status and my treatment experiences for scientific research and clinical evaluation purposes.

My masked personal information may be shared with, and used by, Astellas, so that this information can be analyzed for any future research purpose, including development of new products or improvements to existing treatments.

Signature of Patient or Legal Representative	DD/MM/YYYY
Printed Name of Patient or Legal Representative	
Legal Representative's Relationship to Patient	

☐ I consent to use Personal Information for Future studies

PrVYLOY® (zolbetuximab for injection), in combination with fluoropyrimidine- and platinum-containing chemotherapy, is indicated for:

- the first-line treatment of patients with locally advanced unresectable or metastatic HER2-negative gastric or GEJ adenocarcinoma whose tumours are CLDN 18.2 positive as determined by a validated test.

Consult the Product Monograph at **www.VyloyPM.com** for important information about contraindications, warnings, precautions, adverse reactions, drug interactions, dosing information, and conditions of clinical use not discussed in this piece. The Product Monograph is also available by calling 1-888-338-1824.

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astellas ONCOLOGY

Pr VYLOY® zolbetuximab for injection

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