Merck Care™
Oncology

Program Enrollment Information

MERCK CARE™ Oncology Program

The **MERCK CARE™ Oncology Program** (the "**Program**") is pleased to offer confidential free patient-assistance services, designed for patients who have been prescribed PrKEYTRUDA® (pembrolizumab), which may include, depending on eligibility, reimbursement, compassionate assistance, and/or financial assistance, infusions and/or nursing support services. These services will be presented during an initial call with the **Program** nurse.

The **Program** is available to patients who have been prescribed KEYTRUDA® (pembrolizumab) for the indications described below.

KEYTRUDA® has been issued marketing authorization **without conditions** for:

- Adjuvant treatment of patients with Stage III melanoma with lymph node involvement who have undergone complete resection.

Note: Admittance to the **Program** requires that patients have completed resection within 13 weeks prior to initiating adjuvant therapy (as per the KEYNOTE-054 study design).

- Treatment of patients with metastatic non-squamous NSCLC in combination with pemetrexed and platinum chemotherapy, in adults with no EGFR or ALK genomic tumour aberrations, and no prior systemic chemotherapy treatment for metastatic NSCLC.

Note: Admittance to the **Program** requires that patients have a TPS <50% or an inconclusive result (as determined by a validated test) and no EGFR or ALK genomic tumour aberrations and no prior systemic chemotherapy treatment for metastatic NSCLC.

- Treatment of patients with locally advanced or metastatic urothelial carcinoma, as monotherapy, in adults who have disease progression during or following platinum-containing chemotherapy or within 12 months of completing neoadjuvant or adjuvant platinum-containing chemotherapy.

KEYTRUDA® has been issued marketing authorization **with conditions**, pending the results of studies to verify its clinical benefit. Patients should be advised of the nature of the authorization. An improvement in survival or disease-related symptoms has not yet been established.

KEYTRUDA® is indicated for the treatment of:

- Adult patients with locally advanced unresectable or metastatic urothelial carcinoma, as monotherapy, who are not eligible for cisplatin-containing chemotherapy and whose tumours express PD-L1 (combined positive score [CPS] ≥10) as determined by a validated test†, or in adults who are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status.

Note: Admittance to the **Program** requires that adults are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status and have had no prior systemic chemotherapy for advanced unresectable or metastatic urothelial cancer.

- Adult patients with refractory or relapsed cHL, as monotherapy, who have failed ASCT and BV or who are not ASCT candidates and have failed BV.
- Adult and pediatric patients with refractory PMBCL, or who have relapsed after two or more lines of therapy, as monotherapy.

† The **Program** is not yet available for patients who are not eligible for cisplatin-containing chemotherapy and whose tumours express PD-L1 (CPS ≥10).

ALK=anaplastic lymphoma kinase; ASCT=autologous stem cell transplant; BV=brentuximab vedotin; cHL=classical Hodgkin Lymphoma; CPS=combined positive score; EGFR=epidermal growth factor receptor; NSCLC=non-small cell lung cancer; PD-L1=programmed cell death ligand 1; PMBCL=primary mediastinal B-cell lymphoma; TPS=tumour proportion score

Pr KEYTRUDA® (pembrolizumab)

MERCK CARE™ Oncology Program: Enrollment and Consent Form

Pr KEYTRUDA® (pembrolizumab)

Merck Care™ Oncology

To be completed by the patient (Please print)

First name

Last name

Gender: ☐ F ☐ M Date of birth (DD/MM/YY) / /

Address

City

Province Postal code

Email

Please indicate best telephone number and time to call

Permission to leave a message: ☐ Yes ☐ No

Authorization to speak to patient's caregiver: ☐ Yes ☐ No

Caregiver name (First, Last)

Relationship to the patient

If patient is under 18 years old, to be completed by the legally authorized representative for the patient (Please print)

First name

Last name

Please indicate best telephone number and time to call

Permission to leave a message: ☐ Yes ☐ No

Email

Relationship to the patient

I, THE UNDERSIGNED, HAVE READ AND AGREED TO THE TERMS AND CONDITIONS OF THE PROGRAM FOUND ON THE REVERSE SIDE OF THIS FORM.

Patient's printed name

Patient's signature
or Legally Authorized
Representative's signature

Date (DD/MM/YY) / /

PLEASE FAX THIS COMPLETED FORM TO 1-855-549-9415 OR EMAIL TO keytruda@bayshore.ca

† **Previously untreated metastatic non-squamous NSCLC:** When administering KEYTRUDA® as part of a combination with pemetrexed and platinum chemotherapy, KEYTRUDA® should be administered first. See also prescribing information for pemetrexed and the selected platinum chemotherapy.

To be completed by the physician (Please print)

Physician clinic information

Physician first name **Physician last name** License #

Address

City Province Postal code

Tel. Fax Email

Nurse or drug access coordinator

First name Last name

Tel. Fax Email

Please email/fax "Post-infusion report" and "Medical clarification" to ☐ physician OR ☐ nurse Preferred contact: ☐ Fax ☐ Email ☐ Telephone

Special instructions

Dosage information

Name of prescribed drug: KEYTRUDA® (pembrolizumab) (Please see the product monograph for complete dosing and administration instructions.)

ADULT patient with:	Adult dosage instructions
☐ **Stage III melanoma** (adjuvant therapy) Patient had no prior systemic therapy for melanoma? ☐ Yes ☐ No Patient had no past or current in-transit metastases? ☐ Yes ☐ No Please confirm patient resection was completed within 13 weeks prior to initiating adjuvant therapy ☐ Yes ☐ No	200 mg administered intravenously over 30 minutes every 3 weeks, for ____ cycles, up to one year or until disease recurrence or unacceptable toxicity.
☐ **Previously <u>untreated</u> metastatic non-squamous NSCLC in combination with chemotherapy** No EGFR or ALK genomic tumour aberrations **Patients accepted (pathology report required to validate):** ○ PD-L1 TPS <50% or ○ inconclusive **Note:** If results are pending, a file will be created for the patient; however, enrollment will only be confirmed once TPS results validate patient eligibility.	200 mg administered intravenously over 30 minutes every 3 weeks, for ____ cycles, until disease progression, unacceptable toxicity or up to 24 months in patients without disease progression.†
☐ **Urothelial carcinoma not eligible for any platinum-containing chemotherapy** regardless of PD-L1 status Reason(s) for ineligibility (specify):	
☐ **Previously <u>treated</u> urothelial carcinoma** disease progression during or following platinum-containing chemotherapy or within 12 months of completing neoadjuvant or adjuvant platinum-containing chemotherapy	
☐ **Previously <u>treated</u> relapsed or refractory cHL** failed or is not candidate for ASCT, and failed BV	200 mg administered intravenously over 30 minutes every 3 weeks for ____ cycles.
☐ **Relapsed or refractory PMBCL** after two or more lines of therapy	

PEDIATRIC patient with:	Pediatric dosage instructions
☐ **Relapsed or refractory PMBCL** after two or more lines of therapy	2 mg/kg (up to a maximum of 200 mg) administered intravenously over 30 minutes every 3 weeks for ____ cycles. Dosage requirements: 2 mg/kg x ____ (patient weight) kg = ____ (required dose) mg

For all previously treated patients

Previous therapies:

First infusion date (DD/MM/YY) / /

I, THE UNDERSIGNED, HAVE READ AND AGREED TO THE TERMS AND CONDITIONS OF THE PROGRAM FOUND ON THE REVERSE SIDE OF THIS FORM.

Physician's signature Date (DD/MM/YY) / /

MERCK CARE™ Oncology Program: Enrollment Information

Monday to Friday from 8 a.m. to 8 p.m. EST
Tel.: 1-855-549-9416 Fax: 1-855-549-9415
Email: keytruda@bayshore.ca

Merck Care™ Oncology

Physician's Disclosure and Consent

Please read the information included in the Patient Enrollment Consent section to obtain a full description of the **Program** and, if you agree, sign the form.

- I, the undersigned, have read the Terms and Conditions. I understand the services offered by the **Program** and I represent that (i) I have met with the patient and discussed the **Program** with him/her; (ii) the patient understands the **Program**; (iii) the patient is interested in enrolling in the **Program**; (iv) the patient has consented to me filling out the form and communicating it to the Program Administrator for purposes of enrollment in the **Program**; (v) I explained to the patient that consent for the sharing of coded data with Merck is necessary for the management of the **Program**; and (vi) the patient agrees to be contacted by the Program Administrator to initiate his/her enrollment in the **Program**.
- I understand that I may be contacted at the physician clinic information shared above by the Program Administrator to be provided relevant information related to the services offered to the patient.
- I understand that prescribing information may be used by the Program Administrator or by Merck or its agents for statistical analysis and research purposes relevant for operational and business planning in a manner which will not allow my identification.
- I also consent to be contacted at the physician clinic information provided above by the Program Administrator or its agents for the purpose of inquiring about my experience with the **Program** so that services may be improved and understand that I may request access to the information collected about me to ensure accuracy and correct any mistake or revoke this consent at any time by mailing, emailing or faxing a signed request to the Program Administrator (address: 2101 Hadwen Road, Mississauga, ON, L5K 2L3; email: keytruda@bayshore.ca; fax number: 1-855-549-9415).
- I understand that Merck reserves the right to terminate or modify the **Program** at any time.
- I, the undersigned, certify that my patient's condition is within the indication listed in the current KEYTRUDA® product monograph.
- By providing the name and business coordinates of the Nurse, I represent that I have obtained his/her consent to do so for the purpose of the **Program**.
- I, the undersigned, also agree to the disclosure of appropriate clinical documentation to controllers and auditors contracted by Merck for audit purposes, to the extent that such disclosure is in accordance with the Terms and Conditions.

Patient Enrollment Form/Terms and Conditions of the Program

PLEASE READ THIS CONSENT FORM CAREFULLY BEFORE SIGNING

The Objectives and purposes of the **Program** consist of offering free confidential patient-assistance services, designed for patients who have been prescribed KEYTRUDA® (pembrolizumab). If eligible, you will be provided with reimbursement assistance, compassionate assistance and/or financial assistance, infusions and/or nursing support services.

1. What type of personal information is collected and why?

The Program Administrator needs to collect personal information to determine your eligibility for the **Program**, administer the **Program**, communicate with you and identify you (for example by asking you questions). The information included on this form will be submitted to the Program Administrator by your healthcare provider on your behalf.

In some cases, your personal information (including financial and health information) may be collected from third parties such as your healthcare provider, health insurer, provincial public payer and your caregiver. For example:

- Your medical history and condition and other health information may be obtained from your healthcare provider for the purpose of determining your eligibility to enroll in the **Program**.
- Your health insurance and payment information may be collected from your health insurer for the purpose of assisting you with a reimbursement for which you are eligible.

2. How is your personal information shared?

Third parties assisting with the Program. Your personal information may be exchanged among the Program Administrator, your healthcare provider or health insurer, the provincial public payer, nurses, physicians, pharmacists and your caregiver, when necessary to manage your participation in the **Program**. For example, your health insurance information may be shared by the **Program** with your insurance provider for the purposes of determining your eligibility for reimbursement.

Program sponsor. Merck, the sponsor of the **Program**, may receive: (i) coded information (personal information stripped of its direct identifiers such as your name, address, full date of birth or similar information linked to a secret code) necessary to manage patient enrollment as well as for operational and business planning; as well as (ii) aggregated information (personal information combined with the information of other Program participants without the possibility of identifying you) so that it can perform statistical analysis, identify trends in order to improve the **Program**, and assess patient adherence to treatments and reported health outcomes. It may also receive your personal information, but only when required by law or in the following limited circumstances:

- a complaint is received in connection with the **Program**;
- a healthcare provider either has a special request that would require pre-authorization from Merck or has indicated special instructions on an enrollment form requiring Merck's involvement to coordinate the request;
- there is an adverse event and Merck needs to follow up with your healthcare provider.

3. Where is your personal information stored and how can you access it?

The Program Administrator maintains file(s) containing your personal information in Canada, generally at 2101 Hadwen Road, Mississauga, ON, L5K 2L3. You may request access and correct your personal information by contacting the Program Administrator in writing by mail, fax or email (fax: 1-855-549-9415; email: keytruda@bayshore.ca; mail: see above).

4. What are your choices?

Participation in the **Program** is voluntary but to participate, you must agree to the collection, use and disclosure of your personal information as set out in this form.

Withdrawal of consent for participation in the Program. If you no longer wish to participate in the **Program**, you can contact your healthcare provider, health insurer(s) or the Program Administrator by telephone (1-855-549-9416), by mail, fax or email (see above).

Upon receiving your request, you will no longer be enrolled in the **Program** nor receive assistance with the reimbursement for KEYTRUDA® (pembrolizumab).

I hereby confirm that I wish to enroll in the **Program**, that I have been given the opportunity to discuss the **Program** with my healthcare provider (i.e., doctor or nurse) and that I have read the above **Program** terms and conditions and agree to the collection, use and disclosure of my personal information in accordance with this consent form.

Before prescribing KEYTRUDA®, please consult the product monograph available at www.merck.ca/static/pdf/KEYTRUDA-PM_E.pdf for important information relating to indications, contraindications, warnings, precautions, adverse reactions, drug interactions, dosing and conditions of clinical use which have not been discussed in this document.

The product monograph is also available by calling us at 1-800-567-2594 or by email at medinfocanada@merck.com.

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MEMBER OF INNOVATIVE MEDICINES CANADA

Pr KEYTRUDA® (pembrolizumab)

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