OPDIVO® and YERVOY® ACCESS TO HOPE® Program

Phone: 1-877-967-6626 Fax: 1-800-572-4971 Email: opdivo@bayshore.ca or yervoy@bayshore.ca
The following information is for enrolment purposes only and will be kept confidential.

OPDIVO has been issued marketing authorization **with conditions**, pending the results of trials to verify its clinical benefit, for the treatment of adult patients with:

- Unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor. An improvement in survival or disease-related symptoms has not been established.
- Previously untreated unresectable or metastatic BRAF V600 mutation-positive melanoma. An improvement in survival has not yet been established.
- Previously untreated unresectable or metastatic melanoma when used in combination with ipilimumab. Relative to OPDIVO monotherapy, an increase in progression-free survival (PFS) for the combination of OPDIVO with ipilimumab is established only in patients with low tumour PD-L1 expression (based on the predefined expression level of <5%). An improvement in survival has not yet been established.

Patients should be advised of the nature of the authorization. For further information for OPDIVO please refer to Health Canada's Notice of Compliance with conditions - drug products web site: http://www.hc-sc.gc.ca/dhpmps/prodpharma/notices-avis/conditions/index-eng.php.

OPDIVO has been issued marketing authorization **without conditions** for the treatment of adult patients with:

- Previously untreated unresectable or metastatic BRAF V600 wild-type melanoma.
- Locally advanced or metastatic non-small cell lung cancer (NSCLC) with progression on or after platinum-based chemotherapy. Patients with EGFR or ALK genomic tumour aberrations should have disease progression on a therapy for these aberrations prior to receiving OPDIVO.
- Advanced or metastatic renal cell carcinoma (RCC) who have received prior anti-angiogenic therapy.
- Recurrent or metastatic squamous cell cancer of the head and neck (SCCHN) progressing on or after platinum-based therapy.

YERVOY is indicated for the treatment of unresectable or metastatic melanoma.

To avoid any enrolment delays, please read each section of this form carefully and ensure you fill out every section

PATIENT ENROLMENT FORM

Please check the indication for which you wish to receive assistance:

Unresectable or Metastatic Melanoma (OPDIVO and/or YERVOY) ☐

Locally Advanced or Metastatic Non-Small Cell Lung Cancer* (OPDIVO) ☐

Advanced or Metastatic Renal Cell Carcinoma (OPDIVO) ☐

Recurrent or Metastatic Squamous Cell Cancer of the Head and Neck (OPDIVO) ☐

* Patients with EGFR or ALK genomic tumour aberrations must also have demonstrated disease progression on a therapy for these aberrations prior to receiving OPDIVO.

This patient is seeking reimbursement assistance. ☐

This patient is seeking to pay for his/her treatment. ☐

Service options: ☐ Reimbursement navigation (leave the box unchecked if the site will coordinate reimbursement directly with the insurer if applicable)
☐ Financial assistance ☐ Specialized infusion clinic (coordination of infusion by the ACCESS TO HOPE Program)
☐ Other: _____

Section 1: Patient Information

Preferred language: ☐ English ☐ French

First name: _____ Last name: _____

Address: _____ Apt./Unit: _____

City: _____ Province: _____ Postal code: _____

Email: _____

Home phone: _____ Cellular phone: _____ Office phone: _____

Best time to call: ☐ Day ☐ Evening ☐ Other: _____

Preferred form of contact (check one): ☐ Home phone ☐ Cellular phone ☐ Office phone ☐ Email ☐ Other: _____

Third-party coverage: ☐ Speak to the patient for complete details of his/her insurance program
☐ This patient has the following third-party private insurance coverage:

	Insurer	Name of plan participant	Policy number	Certificate number	Has prior authorization request for reimbursement been sent to the insurer?
Principal insurance plan					☐ Yes ☐ No
Secondary insurance plan					☐ Yes ☐ No

Provincial health card number: _____ Birth date (MM/DD/YYYY): _____/_____/_____ Sex: ☐ M ☐ F

Person to contact in case of emergency: Name: _____ Phone: _____

ECOG Performance Status: ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

Tumour mutational status *(for Melanoma and NSCLC patients only)*: ☐ No Mutation ☐ BRAF+ ☐ ALK+ ☐ EGFR+ ☐ Unknown ☐ Other: _____

Histology: ☐ Squamous NSCLC ☐ Non-squamous NSCLC ☐ Clear cell RCC ☐ Non-clear cell RCC

Selected infusion site/location (if applicable): _____

Please specify all prior systemic therapies (including chemo-radiation) given for advanced or metastatic disease in the order in which they were received (if applicable).

Line of therapy	Therapy or treatment regimen (please indicate treatment start date, stop date and reason for discontinuation if available)
First-line	
Second-line	
Third-line	

Confirmation of patient eligibility:

For OPDIVO or OPDIVO + YERVOY in previously untreated melanoma: The patient has not received any prior systemic therapy for unresectable or metastatic disease ☐

For OPDIVO monotherapy in previously treated melanoma: Disease progression was observed on/after ipilimumab and if BRAF V600 mutation positive, a BRAF inhibitor ☐

For YERVOY monotherapy: Patient has unresectable or metastatic melanoma ☐

For OPDIVO monotherapy in previously treated NSCLC: Disease progression was observed on/after a platinum-based chemotherapy
(Patients with EGFR or ALK genomic tumour aberrations should have disease progression on a therapy for these aberrations prior to receiving OPDIVO) ☐

For OPDIVO monotherapy in previously treated RCC: Patient has received prior anti-angiogenic therapy ☐

For OPDIVO monotherapy in previously treated SCCHN: Disease progression was observed on/after platinum-based therapy ☐

Section 2: Patient Consent

I have read and agree to the terms and conditions of the OPDIVO ACCESS TO HOPE Program **and the privacy statement within this form.** ☐

PATIENT CONSENT _____ _____/_____/_____
Patient's signature Date (MM/DD/YYYY)

Patient has provided verbal consent ☐ _____/_____/_____
Date (MM/DD/YYYY)

Verbal consent obtained by: Name: _____ Title: _____

Consent has been obtained to leave a message at the contact information provided above ☐

I also consent to having the following person speak or be spoken to on my behalf:

First name: _____ Last name: _____

Email: _____

Home phone: _____ Cellular phone: _____ Office phone: _____

_____ _____/_____/_____
Patient's signature Date (MM/DD/YYYY)

Section 3: Prescription Information and Physician Authorization

Complete the prescription below and fax to the OPDIVO and YERVOY ACCESS TO HOPE Program **at 1-800-572-4971**. I authorize the Program Administrator in the context of the Program to be my designated agent to forward the prescription by fax or other mode of delivery to the pharmacy chosen by the above-named patient. This prescription represents the original prescription drug order. The original prescription will not be reused.

℞ Prescription information

OPDIVO (nivolumab) monotherapy

The recommended dose of OPDIVO is 3 mg/kg administered intravenously over 60 minutes every 2 weeks. ☐

Treatment should be continued as long as clinical benefit is observed or until treatment is no longer tolerated by the patient.

Dosage per infusion:

3 mg/kg x _____ kg = _____ mg every 2 weeks

Number of repeats: _____

MELANOMA PATIENTS ONLY

YERVOY (ipilimumab) monotherapy

The recommended dose of YERVOY is 3 mg/kg administered intravenously over 90 minutes every 3 weeks for a total of 4 doses. ☐

Patients should receive all 4 doses as tolerated, regardless of the appearance of new lesions or growth of existing lesions.

Dosage per infusion:

3 mg/kg x _____ kg = _____ mg every 3 weeks

Number of repeats: 4

MELANOMA PATIENTS ONLY

OPDIVO (nivolumab) + YERVOY (ipilimumab) ☐

REGIMEN

The recommended dose of OPDIVO during the combination phase is 1 mg/kg administered intravenously over 60 minutes every 3 weeks for 4 doses in combination with YERVOY 3 mg/kg administered intravenously over 90 minutes.

This is followed by the single-agent phase, during which the recommended dose of OPDIVO is 3 mg/kg administered intravenously over 60 minutes every 2 weeks. Treatment should be continued as long as clinical benefit is observed or until treatment is no longer tolerated by the patient.

COMBINATION PHASE:

Dosage per OPDIVO infusion: 1 mg/kg x _____ kg = _____ mg every 3 weeks

Dosage per YERVOY infusion: 3 mg/kg x _____ kg = _____ mg every 3 weeks

Number of repeats: 4

SINGLE-AGENT PHASE:

Dosage per infusion: 3 mg/kg x _____ kg = _____ mg every 2 weeks

Number of repeats: _____

PHYSICIAN AUTHORIZATION

I certify that I am the physician who has prescribed the medication selected to the patient identified at the dose selected.

_____ Physician's signature

_____ Physician license number

_____/_____/_____ Date (MM/DD/YYYY)

Section 4: Physician Information

First name: _____ Last name: _____

Address: _____

City: _____ Province: _____ Postal code: _____

Office phone: _____ Office fax: _____ Email: _____

Affiliation: _____

Preferred form of contact (check one): ☐ Office phone ☐ Office fax ☐ Email ☐ Other: _____

Section 5: Primary Patient Coordinator (person responsible for patient services, including: enrolment, reimbursement and coordination of infusions)

First name: _____ Last name: _____

Office phone: _____ Office fax: _____ Email: _____

Affiliation: _____

Section 6: Primary Pharmacy Contact (required only if treatment will be administered at your institution)†

First name: _____ Last name: _____

Office phone: _____ Office fax: _____ Email: _____

Shipping information

Ship to (address): _____

† Some private plans may only accept to fund the treatment if it is not delivered in hospital

Please consult the Product Monographs at http://www.bmscanada.ca/static/products/en/pm_pdf/OPDIVO_EN_PM.pdf and http://www.bmscanada.ca/static/products/en/pm_pdf/YERVOY_EN_PM.pdf for contraindications, warnings, precautions, adverse reactions, interactions, dosing, and conditions of clinical use. The Product Monographs are also available by calling us at: 1-866-463-6267.

PATIENT CONSENT TO ENROLMENT

I confirm that the information I have provided in this application for enrolment into the OPDIVO and/or YERVOY ACCESS TO HOPE Program ("Program") is complete and accurate. I would like to enrol in the Program and receive educational and therapy support services designed for people taking OPDIVO and/or YERVOY provided by the Program. The Program is a customer service program currently administered by Bayshore HealthCare Ltd., a third-party provider of client-focused services and patient support programs ("Administrator"), and sponsored by Bristol-Myers Squibb Canada ("BMS"). I understand that BMS reserves the right at any time and without notice to modify the enrolment form or the Program, including its eligibility criteria and any other aspects of the Program or to discontinue the Program and terminate assistance.

I understand that one of the services provided by the Program may include, based on eligibility, assistance in coordinating reimbursement and/or financial assistance, compassionate use, infusions and nursing assistance for OPDIVO and/or YERVOY infusions. I authorize my physician and my health insurance company to disclose to the Administrator and its authorized representatives my personal information, including my name, address, phone number, email address and personal health information relating to my medical condition, medical history, treatment, or financial information such as my insurance coverage. I authorize my personal information, including my personal health information, to be used by the Administrator for purposes of verifying my insurance coverage for OPDIVO and/or YERVOY and/or otherwise arranging for reimbursement for OPDIVO and/or YERVOY, coordinating delivery of OPDIVO and/or YERVOY to me, arranging training on or assistance with the administration of OPDIVO and/or YERVOY and providing me with other educational and support services associated with OPDIVO and/or YERVOY therapy (the "Services"). For the purpose of providing the Services of the Program, I hereby authorize and instruct the Administrator to obtain any medical and personal information relating to my enrolment in the Program from me, my authorized representatives, my prescribing physician(s), pharmacist(s), private insurance company(ies), public payer(s) and any other healthcare provider or payer that may possess the necessary information. For the Program to provide me with the Services, my personal information may be collected, used and disclosed only as necessary for the delivery of care or support to me and in accordance with applicable law. I acknowledge that my personal information may be shared with persons involved in the Program and my treatment (i.e., Administrator and its authorized representatives and agents, my physician, pharmacists and other healthcare providers), or for providing and coordinating other Program Services for me or for purposes authorized by applicable law, unless I otherwise expressly so advise.

In addition, if at any time and for any reason BMS appoints a new administrator to replace the Administrator, I hereby consent to the transfer of my personal information by the Administrator to another third-party administrator for the purpose of continuing my participation in the Program. I also consent to the transfer of my personal information by the Administrator to any other "third-party" for purposes relating to the offering by the Program of additional Program features and services (such as tools, web sites, mobile applications to manage my health condition).

With respect to BMS, I understand that non-personally identifiable information regarding Program participation and outcomes may be presented to BMS for its use. I authorize BMS to publish in scientific publications (e.g., medical journals or scientific conferences) the information it obtains through this program. Examples of publication content include, but are not limited to, data on previous drug use, drug retention rates, and disease progression. Rest assured that any personal information that could identify you will be removed before any information is shared with BMS so none of your personal information will be disclosed for the purposes of any publication nor will it be part of any publication. I also understand that BMS has a legal requirement to report any adverse drug events to Health Canada and I hereby authorize BMS to collect information on any adverse drug events I may experience while on OPDIVO and/or YERVOY in order to monitor its safety, meet its reporting requirements and to continuously assess its benefit-risk profile. My personal information and details of any adverse drug event occurring while on treatment with OPDIVO and/or YERVOY can be communicated to the Administrator and to BMS Pharmacovigilance. I also consent to BMS contacting my physician in case any further clarification regarding the adverse drug event is needed. I understand that all the information provided to BMS will be stored in the corporate safety database located in the United States for the period of time mandated by law, and may be shared with its group companies and regulatory authorities as required by laws and regulations.

With respect to the personal information collected as part of my enrolment and participation in the Program, I understand that I may contact the Administrator of the Program to speak with the Administrator's Privacy Officer for more information, to address any additional questions I may have and to find out how I can access my personal information.

I am aware that it is my right to refuse to sign the consent form and to refuse the collection, use and disclosure of my personal information, as outlined above, and that if I do not provide consent, I may not be eligible for the Program Services. I understand that I may cancel my enrolment and this consent at any time by mailing or faxing a signed request to the Program Administrator:

Bayshore HealthCare Ltd. 2101 Hadwen Road, Mississauga, ON L5K 2L3
Fax: 1-800-572-4971

My cancellation will be in effect upon receipt of the letter by the Administrator of the Program and any further collection, use and disclosure of my personal information will cease.