Drug Prior Authorization Form
Keytruda (pembrolizumab)

The purpose of this form is to obtain information required to assess your drug claim.

IMPORTANT: Please answer all questions. Your claim assessment will be delayed if this form is incomplete or contains errors.

Any costs incurred for the completion of this form are the responsibility of the plan member/patient.

Canada Life recognizes and respects the importance of privacy. Personal information collected is used for the purposes of assessing eligibility for this drug and for administering the group benefits plan. For a copy of our Privacy Guidelines, or if you have questions about Canada Life's personal information policies and practices (including with respect to service providers), refer to canadalife.com or write to Canada Life's Chief Compliance Officer.

I authorize Canada Life, any healthcare provider, my plan administrator, any insurance or reinsurance company, administrators of government benefits or patient support programs or other benefits programs, other organizations, or service providers working with Canada Life or any of the above, located inside or outside Canada, to exchange personal information when relevant and necessary for these purposes. I understand that personal information may be subject to disclosure to those authorized under applicable law within or outside Canada.

I acknowledge that the personal information is needed to assess eligibility for this drug and to administer the group benefits plan. I acknowledge that providing consent will help Canada Life to assess my claim and that refusing to consent may result in delay or denial of my claim. Canada Life reserves the right to audit the information provided on this form at any time and this consent extends to any audit of my claim. This consent may be revoked by me at any time by sending written instruction to that effect.

I also consent to the use of my personal information for Canada Life and its affiliates' internal data management and analytics purposes.

If the patient is a person other than myself, I confirm that the patient has given their consent to provide their personal information and for Canada Life to use and disclose it as set out above.

I certify that the information given below is true, correct, and complete to the best of my knowledge. Failure to provide true, correct and complete information on this form could result in revocation of any approval decision, a requirement to repay paid claims or other appropriate action.

Plan Member's signature: _____ Date: _____

Form Completion Instructions:

1. **Complete "Patient Information" sections.**
2. **Have the prescribing physician complete the "Physician Information" sections.**
3. **Send all pages of the completed form to us by mail, fax or email as noted below.**

Note: As email is not a secure medium, any person with concerns about their prior authorization form/medical information being intercepted by an unauthorized party is encouraged to submit their form by other means.

Mail to: **The Canada Life Assurance Company**
Drug Claims Management
PO Box 6000
Winnipeg MB R3C 3A5

Fax to: **The Canada Life Assurance Company**
Fax 1-204-946-7664
Attention: Drug Claims Management

Email to: **cldrug.services@canadalife.com**
Attention: Drug Claims Management

For additional information regarding Prior Authorization and Health Case Management, please visit our Canada Life website at canadalife.com or contact Group Customer Contact Services at 1-800-957-9777. Deaf or hard of hearing and require access to a telecommunications relay service? Please contact us at 711 for TTY to Voice or 1-800-855-0511 for Voice to TTY.

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Patient Information
Keytruda (pembrolizumab)

Plan Member Information – Complete all sections of this page (please print)

Plan Member:	Patient Name:	
Plan Name:	Plan Number:	Plan Member ID Number:
Patient Date of Birth (DD/MM/YYYY):	Address (number, street, city, province, postal code):	

Please indicate preferred contact number and if there are any times when telephone contact with you about your claim would be most convenient.

May we contact you by email? (Note that some correspondence may still need to be sent by regular mail).

☐ Yes ☐ No If yes, please provide email address: _____

Tell us if you have been on this drug before

Is the patient currently on, or previously been on this drug? ☐ Yes ☐ No

If Yes, a) indicate start date (DD/MM/YYYY): _____

b) coverage provided by: _____

(if coverage is not provided by Canada Life please provide pharmacy print-out showing purchase of this drug)

Tell us if you have coverage with any other benefits plan

Does the patient have drug coverage under any other group benefits plan? ☐ Yes ☐ No

If Yes, name of other Insurance Company: _____

If other plan is with Canada Life, tell us the plan and ID number: _____

Name of plan member: _____

Relationship to patient: _____

Provide details and attach documentation of acceptance or decline:

_____

_____

Tell us about any Provincial or other coverage you may have

Does the patient have coverage under a provincial program or from any other source? ☐ Yes ☐ No

If Yes, name of program or other source: _____

Provide details and attach documentation of acceptance or decline: _____

Is the patient currently receiving disability benefits for the condition for which this drug has been prescribed? ☐ Yes ☐ No

Tell us about any Patient Support Program you might be enrolled in

Has the patient enrolled in the patient support program for this drug? ☐ Yes ☐ No

If Yes, please provide the following information:

1. Patient support program patient ID Number: _____
2. Patient support program contact person name and phone number:

   Contact Name: _____ Phone Number: _____

(Continued on next page)

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Physician Information
Keytruda (pembrolizumab)

Note to Physician: In order to assess a patient's claim for Keytruda, we require detailed information on the patient's prescription drug history as requested below.

Attach extra information if necessary. *GENETIC TEST RESULTS ARE NOT REQUIRED.*

Physician's Information (please print)

Name of prescribing physician:

Specialty:

Address (number, street, city, province, postal code):

Telephone Number (including area code):	Fax Number (including area code):

1. Is this drug being prescribed in accordance with approved Health Canada indications[1]?

☐ Yes, complete questions 1 - 8 and Physician's Information

☐ No, condition not approved by Health Canada: _____

Complete questions 1 - 8 and Off-label use

Please select the indication Keytruda is being used for:

☐ Bladder cancer
☐ Breast cancer, early stage
☐ Breast cancer, unresectable/metastatic, first line
☐ Cervical cancer
☐ Classical Hodgkin Lymphoma
☐ Colorectal cancer, unresectable/metastatic, first line
☐ Colorectal cancer, unresectable/metastatic, second line or more
☐ Endometrial cancer, monotherapy
☐ Endometrial cancer, with lenvatinib
☐ Esophageal cancer
☐ Head and neck squamous cell carcinoma (HNSCC)
☐ Melanoma, adjuvant, stage IIb or IIc
☐ Melanoma, adjuvant, stage III
☐ Melanoma, unresectable/metastatic
☐ Non-small cell lung cancer, metastatic, first line, in combination
☐ Non-small cell lung cancer, metastatic, monotherapy, first line
☐ Non-small cell lung cancer, metastatic, monotherapy, second line or more
☐ Primary mediastinal B-cell Lymphoma (PMBCL)
☐ Renal cell carcinoma, adjuvant
☐ Renal cell carcinoma, metastatic, in combination with axitinib
☐ Renal cell carcinoma, metastatic, in combination with lenvatinib
☐ Urothelial carcinoma, unresectable/metastatic, not eligible for cisplatin
☐ Urothelial carcinoma, unresectable/metastatic, progressed after platinum chemo

☐ Other (approved by Health Canada): _____

Complete questions 1 - 8 and Other condition (Health Canada approved)

(Continued on next page)

Physician Information
Keytruda (pembrolizumab)

Physician's Information *(continued)* (please print)

2. Prescribed dosage and regimen:
   - ☐ 200mg administered intravenously every 3 weeks
   - ☐ 400mg administered intravenously every 6 weeks
   - ☐ 2mg/kg administered intravenously every 3 weeks
   - ☐ Other (please specify): _____
     Provide rationale: _____

   Patient's weight: _____ kg (for weight-based dosing)

   Date determined (MM/YYYY): _____
3. Please provide date of initial diagnosis (MM/YYYY): _____
4. What is the patient"s ECOG score: _____
5. What is the anticipated duration of treatment with this drug? _____
6. Where will treatment be administered? ☐ Home ☐ Physician's Office ☐ Private clinic ☐ Hospital in-patient ☐ Hospital out-patient
7. Please provide medical rationale why Keytruda has been prescribed instead of an alternative drug in the same therapeutic class:

   Genetic test results are not required

   _____

   _____
8. Drug and Treatment History – **must be completed for every request.**

Drug(s) and Treatment(s) past and present	Dosing Regimen	Start Date (DD/MM/YYYY)	End Date (DD/MM/YYYY)	Clinical Results/Outcome
				☐ Failure ☐ Intolerance ☐ Other Clinical details:
				☐ Failure ☐ Intolerance ☐ Other Clinical details:
				☐ Failure ☐ Intolerance ☐ Other Clinical details:

Bladder Cancer – Genetic test results are not required

Has the patient previously received BCG therapy? ☐ Yes ☐ No

If yes, please provide details in the Drug and Treatment history chart.

Is the patient's bladder cancer considered to be non-muscle invasive? ☐ Yes ☐ No

Is the patient's bladder cancer considered to be high-risk? ☐ Yes ☐ No

Has the patient received a radical cystectomy? ☐ Yes ☐ No

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Physician Information
Keytruda (pembrolizumab)

Physician's Information *(continued)* (please print)

Breast Cancer, early stage – Genetic test results are not required

Will Keytruda be used in combination with chemotherapy in the neoadjuvant setting, and as monotherapy in the adjuvant setting? ☐ Yes ☐ No

Is patient's cancer considered stage II or III? ☐ Yes ☐ No

Is Keytruda being used in the first line setting? ☐ Yes ☐ No

Breast Cancer, unresectable/metastatic – Genetic test results are not required

Will Keytruda be used in combination with chemotherapy? ☐ Yes ☐ No

Has patient received prior chemotherapy for metastatic disease? ☐ Yes ☐ No

Cervical Cancer – Genetic test results are not required

Has patient received prior chemotherapy? ☐ Yes ☐ No

If yes, please provide details in the Drug and Treatment history chart.

Will Keytruda be used in combination with chemotherapy? ☐ Yes ☐ No

Will Keytruda be used in combination with bevacizumab? ☐ Yes ☐ No

If yes, please indicate:

_____

_____

The patient's weight: _____

Prescribed dosage and regimen for bevacizumab: _____

Is coverage for bevacizumab being requested? ☐ Yes ☐ No

Please note, a separate Prior Authorization form does not need to be completed for bevacizumab.

Classical Hodgkin Lymphoma – Genetic test results are not required

Has the patient failed an autologous stem cell transplant? ☐ Yes ☐ No

If yes, please provide details in the Drug and Treatment history chart.

If no, ins ASCT contraindicated in this patient? ☐ Yes ☐ No

Colorectal Cancer, metastatic, first line – Genetic test results are not required

Will Keytruda be used as monotherapy? ☐ Yes ☐ No

Will Keytruda be used as the first line treatment of metastatic colorectal cancer? ☐ Yes ☐ No

Colorectal Cancer, unresectable/metastatic, second line or more – Genetic test results are not required

Will Keytruda be used as monotherapy? ☐ Yes ☐ No

Please complete the Drug and Treatment chart.

Endometrial Cancer, with lenvatinib – Genetic test results are not required

Will Keytruda be used in combination with lenvatinib? ☐ Yes ☐ No

Is patient's endometrial cancer advanced or metastatic? ☐ Yes ☐ No

Has the patient experienced disease progression after platinum-based chemotherapy? ☐ Yes ☐ No

If yes, please provide details in the Drug and Treatment history chart.

Is patient a candidate for curative surgery or radiation? ☐ Yes ☐ No

Physician Information
Keytruda (pembrolizumab)

Physician's Information (*continued)* (please print)

Endometrial Cancer, monotherapy – Genetic test results are not required

Will Keytruda be used as monotherapy? ☐ Yes ☐ No

Has patient's tumour progressed following prior therapy? ☐ Yes ☐ No

Esophageal Cancer – Genetic test results are not required

Will Keytruda be used in combination with platinum and fluoropyrimidine based chemotherapy? ☐ Yes ☐ No

Will Keytruda be used as the first line treatment of locally advanced, unresectable, or metastatic disease? ☐ Yes ☐ No

Head and Neck Squamous Cell Carcinoma – Genetic test results are not required

Is the patient's head and neck squamous cell carcinoma considered metastatic or unresectable recurrent? ☐ Yes ☐ No

Has patient received previous therapy for their metastatic or unresectable recurrent head and neck squamous cell carcinoma? ☐ Yes ☐ No

Indicate which applies to the patient:

☐ Keytruda will be used as monotherapy

☐ Keytruda will be used in combination with platinum and fluorouracil chemotherapy

Melanoma – adjuvant treatment – Genetic test results are not required

Indicate which applies to the patient:

☐ Stage IIb/IIc melanoma

☐ Stage III melanoma with lymph node involvement

Has patient undergone complete resection of their melanoma? ☐ Yes ☐ No

Will Keytruda be used as monotherapy? ☐ Yes ☐ No

Melanoma – Unresectable/Metastatic – Genetic test results are not required

Will Keytruda be used as monotherapy? ☐ Yes ☐ No

Non-small cell lung cancer – advanced/metastatic, in combination – Genetic test results are not required

Please indicate which applies to the patient's NSCLC:

☐ squamous

☐ non-squamous

Please indicate which chemotherapy Keytruda will be combined with:

☐ pemetrexed and platinum chemotherapy

☐ carboplatin and paclitaxel/nab-paclitaxel

Is Keytruda being used in the first-line setting? ☐ Yes ☐ No

Non-small cell lung cancer - advanced/metastatic, monotherapy - Genetic test results are not required

Is Keytruda being used in the first line setting? ☐ Yes ☐ No

Is Keytruda being used in the second-line setting or beyond? ☐ Yes ☐ No

Please ensure Drug and Treatment History chart is completed

Is Keytruda being used as monotherapy? ☐ Yes ☐ No

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Physician Information
Keytruda (pembrolizumab)

Physician's Information (*continued)* (please print)

Primary Mediastinal B-cell Lymphoma (PMBCL)– Genetic test results are not required

Does the patient have relapsed or refractory primary mediastinal large B-cell lymphoma? ☐ Yes ☐ No

Indicate which applies to the patient:

- ☐ Patient has relapsed after an autologous stem cell transplant
- ☐ Patient is ineligible for ASCT and has received >2 lines of prior therapy

Please complete the Drug and Treatment History chart.

Will Keytruda be used as monotherapy? ☐ Yes ☐ No

Renal Cell Carcinoma – Adjuvant - Genetic test results are not required

Has patient undergone a nephrectomy? ☐ Yes ☐ No

Is patient's RCC considered at intermediate-high or high risk of recurrence or M1 no evidence of disease (NED)? ☐ Yes ☐ No

Has patient received prior systemic therapy for their RCC? ☐ Yes ☐ No

Will Keytruda be used as monotherapy? ☐ Yes ☐ No

Renal Cell Carcinoma, Metastatic - Genetic test results are not required

Indicate which applies to the patient:

- ☐ Keytruda will be used in combination with axitinib
- ☐ Keytruda will be used in combination with lenvatinib

Has patient received prior chemotherapy for their advanced/metastatic renal cell carcinoma? ☐ Yes ☐ No

Urothelial Carcinoma (UC) – Previously treated- Genetic test results are not required

Does the patient have a histologically or cytologically confirmed diagnosis of locally advanced, unresectable, or metastatic urothelial carcinoma in the renal pelvis, ureter, bladder or urethra? ☐ Yes ☐ No

Has patient received prior lines of systemic chemotherapy for advanced disease? ☐ Yes ☐ No

If yes, how many lines of therapy?_____

Has disease progressed after treatment using platinum-based chemotherapy or recurred after 12 months of completion of platinum-based chemotherapy? ☐ Yes ☐ No

Please indicate the number of measurable lesions according to RECIST v1.1: _____

Urothelial Carcinoma (UC) – Ineligible for platinum-based chemotherapy - Genetic test results are not required

Does the patient have a histologically or cytologically confirmed diagnosis of locally advanced, unresectable, or metastatic urothelial carcinoma in the renal pelvis, ureter, bladder or urethra? ☐ Yes ☐ No

Is the patient considered ineligible for platinum-based chemotherapy? ☐ Yes ☐ No

Has patient previously received any other chemotherapy for the treatment of advanced disease? ☐ Yes ☐ No

Will Keytruda be used as monotherapy? ☐ Yes ☐ No

Other condition (Health Canada approved) – Genetic test results are not required

Please provide any relevant information related to the disease and attach supporting documentation.

_____

_____

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Physician Information
Keytruda (pembrolizumab)

Physician's Information (*continued)* (please print)

Renewal Request – Genetic test results are not required

IStart date of treatment (MM/YYYY): _____

Describe the patient's response to treatment, particularly in relation to the signs and symptoms of their disease at initial presentation. Attach copies of relevant test results, specialist's consultation or clinical notes

_____

_____

Has there been confirmed progression since initiation of Keytruda therapy? ☐ Yes ☐ No

Off-label use – Genetic test results are not required

Questions 1 – 8 must be completed.

Date of initial diagnosis (DD/MM/YYYY): _____

Is there clinical evidence supporting the off-label use of this drug? ☐ Yes ☐ No

Provide clinical literature/studies to support the request for off-label use, such as:

- At least two Phase II or two Phase III clinical trials showing consistent results of efficacy; and
- Published recommendations in evidence-based guidelines supporting its use.

Provide medical rationale why this drug has been prescribed off-label instead of an alternate drug with an approved indication for this condition.

_____

_____

Provide any pertinent medical history or information to support this off-label request.

_____

_____

If this is a renewal request, provide documentation showing treatment efficacy since previous request.

_____

_____

Physician Information
Keytruda (pembrolizumab)

Note for Physician: To be eligible for reimbursement, Canada Life may require your patient to purchase a drug requiring prior authorization from a pharmacy designated by Canada Life. If applicable, a health case manager will contact you with further information.

I certify that the information provided is true, correct, and complete.

Physician's Signature: _____ Date: _____

License Number: _____

It is important to provide the requested information in detail to help avoid delay in assessing claims for the above drug. This form may be subject to audit. The completed form can be returned to Canada Life by mail, fax, or email.

Note: As email is not a secure medium, any person with concerns about their prior authorization form/medical information being intercepted by an unauthorized party is encouraged to submit their form by other means.

Mail to: **The Canada Life Assurance Company**
Drug Claims Management
PO Box 6000
Winnipeg MB R3C 3A5

Email to: **cldrug.services@canadalife.com**
Attention: Drug Claims Management

Fax to: **The Canada Life Assurance Company**
Fax 1-204-946-7664
Attention: Drug Claims Management

[1]*Approved Health Canada Indications for Keytruda:*

- Adult patients with Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in-situ (CIS) with or without papillary tumours who are ineligible for or have elected not to undergo cystectomy.
- Adult patients in combination with chemotherapy with locally recurrent unresectable or metastatic triple-negative breast cancer (TNBC), who have not received prior chemotherapy for metastatic disease and whose tumors express PD-L1 (Combined Positive Score [CPS] ≥ 10) as determined by a validated test.
- Treatment of adult patients with high-risk early-stage triple-negative breast cancer (TNBC) in combination with chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment after surgery.
- Treatment of adult patients with persistent, recurrent, or metastatic cervical cancer whose tumours express PD-L1 (CPS ≥ 1) as determined by a validated test, in combination with chemotherapy with or without bevacizumab.
- Adult and pediatric patients with refractory or relapsed classical Hodgkin Lymphoma (cHL), as monotherapy, who have failed autologous stem cell transplant (ASCT) or who are not candidates for multi-agent salvage chemotherapy and ASCT.
- In combination with lenvatinib, adult patients with advanced endometrial carcinoma that is not microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR), who have disease progression following prior platinum-based systemic therapy, and are not candidates for curative surgery or radiation.
- First-line treatment of locally advanced unresectable or metastatic, carcinoma of the esophagus or HER2 negative adenocarcinoma of the esophagogastric junction (tumour centre 1 to 5 centimetres above the gastric cardia) in combination with platinum and fluoropyrimidine based chemotherapy, in adult patients.
- First-line treatment of metastatic or unresectable recurrent head and neck squamous cell carcinoma (HNSCC) as monotherapy, in adult patients whose tumours have PD-L1 expression [Combined Positive Score (CPS) ≥1] as determined by a validated test.
- First-line treatment of metastatic or unresectable recurrent head and neck squamous cell carcinoma (HNSCC) in combination with platinum and fluorouracil (FU) chemotherapy, in adult patients.
- Adjuvant treatment of adult and pediatric (12 years and older) patients with Stage IIB or IIC melanoma following complete resection.
- Adjuvant treatment of patients with Stage III melanoma with lymph node involvement who have undergone complete resection.
- Treatment of patients with unresectable or metastatic melanoma who have not received prior treatment with ipilimumab. Subjects with BRAF V600 mutant melanoma may have received prior BRAF inhibitor therapy.
- Treatment of patients with unresectable or metastatic melanoma and disease progression following ipilimumab therapy and, if BRAF V600 mutation positive, following a BRAF or MEK inhibitor.
- Colorectal cancer whose tumours have progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan, as monotherapy.
- Endometrial cancer whose tumours have progressed following prior therapy and who have no satisfactory alternative treatment options, as monotherapy.
- First-line treatment, as monotherapy, of adult patients with metastatic MSI-H or dMMR colorectal cancer (CRC)
- 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.

[1]*Approved Health Canada Indications for Keytruda:*

- Treatment of patients with metastatic squamous NSCLC in combination with carboplatin and either paclitaxel or nab-paclitaxel, in adults with no prior systemic chemotherapy treatment for metastatic NSCLC.
- First-line treatment, as monotherapy, of adults with metastatic non-small cell lung carcinoma (NSCLC) or stage III disease where patients are not candidates for surgical resection or definitive chemoradiation, expressing PD-L1 [Tumour Proportion Score (TPS ≥1%)] as determined by a validated test, with no EGFR or ALK genomic tumour aberrations.
- Adult patients with metastatic non-small cell lung carcinoma (NSCLC) as monotherapy, whose tumours express PD-L1 [(Tumour Proportion Score (TPS) ≥ 1%)] as determined by a validated test and who have disease progression on or after platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumour aberrations should have received authorized therapy for these aberrations prior to receiving Keytruda.
- Adult and pediatric patients with refractory Primary Mediastinal B-cell Lymphoma (PMBCL) or who have relapsed after 2 or more lines of therapy, as monotherapy.
- Treatment of patients with advanced or metastatic renal cell carcinoma (RCC) in combination with axitinib, in adults with no prior systemic therapy for metastatic RCC.
- Treatment of adult patients with advanced (not amenable to curative surgery or radiation) or metastatic RCC in combination with lenvatinib with no prior systemic therapy for metastatic RCC.
- Adult patients with locally advanced unresectable or metastatic urothelial carcinoma, as monotherapy, who are not eligible for any cisplatin-containing chemotherapy
- 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.