

Drug Prior Authorization Form Keytruda (pembrolizumab)

The purpose of this form is to obtain information required to assess your drug claim. Approval for coverage of this drug may be reassessed at any time at Great-West Life's discretion. For additional information regarding Prior Authorization and Health Case Management, please visit our Great-West Life website at www.greatwestlife.com.

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.

Great-West 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 Great-West Life's personal information policies and practices (including with respect to service providers), refer to www.greatwestlife.com or write to Great-West Life's Chief Compliance Officer.

I authorize Great-West Life, any healthcare provider, my plan administrator, any insurance or reinsurance company, administrators of government benefits or patient assistance programs or other benefits programs, other organizations, or service providers working with Great-West 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 Great-West Life to assess my claim and that refusing to consent may result in delay or denial of my claim. Great-West 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.

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 Great-West 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 Great-West Life Assurance Company
Drug Services
PO Box 6000
Winnipeg MB R3C 3A5

Fax to: The Great-West Life Assurance Company
Fax 1-204-946-7664
Attention: Drug Services

Email to: gwldrug.services@gwl.ca
Attention: Drug Services

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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 Keytruda? Yes No

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

b) coverage provided by: _____

(if coverage is not provided by Great-West 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 Great-West Life, tell us the plan and ID number: _____

Name of plan member: _____

Relationship to patient: _____

Provide details and attach documentation of acceptance or declination:

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 declination: _____

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

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

Has the patient enrolled in the patient assistance program for Keytruda drug? Yes No

If Yes, please provide the following information:

1. Patient assistance program patient ID Number: _____

2. Patient assistance program contact person name and phone number:

Contact Name: _____ Phone Number: _____

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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 indications¹?

Yes, complete questions 1 - 7 and Physician's Information

No, condition not approved by Health Canada: _____

Complete questions 1 - 7 and Off-label use

¹Approved Health Canada Indications and Clinical Use for Keytruda

Classical Hodgkin Lymphoma (cHL)

¹Adult patients with refractory or relapsed classical Hodgkin Lymphoma (cHL), as monotherapy, who have failed autologous stem cell transplant (ASCT) and brentuximab vedotin (BV) or who are not ASCT candidates and have failed BV.

Melanoma

¹Adjuvant treatment of patients with Stage III melanoma with lymph node involvement who have undergone complete resection.

¹Treatment 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.

¹Treatment 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.

Microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)

¹Colorectal cancer whose tumours have progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan, as monotherapy.

¹Endometrial cancer whose tumours have progressed following prior therapy and who have no satisfactory alternative treatment options, as monotherapy.

Non-small cell lung carcinoma (NSCLC)

¹Treatment 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.

¹Treatment 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.

¹Treatment of patients with metastatic non-small cell lung carcinoma (NSCLC) as monotherapy, in adults whose tumours have high PD-L1 expression (TPS ≥50%) as determined by a validated test, with no EGFR or ALK genomic tumour aberrations, and no prior systemic chemotherapy treatment for metastatic NSCLC.

¹Adult 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.

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Physician's Information (continued) (please print)

Primary Mediastinal B-cell Lymphoma (PMBCL)

¹Adult and pediatric patients with refractory Primary Mediastinal B-cell Lymphoma (PMBCL) or who have relapsed after 2 or more lines of therapy, as monotherapy.

Urothelial carcinoma

¹Adult patients with locally advanced unresectable or metastatic urothelial carcinoma, as monotherapy, who are not eligible for cisplatin-containing chemotherapy and whose tumors 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.

¹Treatment 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.

Other (approved by Health Canada): _____

Complete questions 1 - 7 and Other condition (Health Canada approved)

2. Prescribed dosage and regimen:

200mg administered intravenously every 3 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 anticipated duration of treatment with this drug? _____

5. Where will treatment be administered? Home Physician's Office Private clinic Hospital in-patient Hospital out-patient

6. Please provide medical rationale why Keytruda drug has been prescribed instead of an alternative drug in the same therapeutic class:

Genetic test results are not required

7. 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
				<input type="checkbox"/> Failure <input type="checkbox"/> Intolerance <input type="checkbox"/> Other Clinical details: _____ _____
				<input type="checkbox"/> Failure <input type="checkbox"/> Intolerance <input type="checkbox"/> Other Clinical details: _____ _____
				<input type="checkbox"/> Failure <input type="checkbox"/> Intolerance <input type="checkbox"/> Other Clinical details: _____ _____

Physician's Information (continued) (please print)

Unresectable/Metastatic Melanoma – Genetic test results are not required

Is Keytruda being used in first-line setting second-line setting other

If being used in the second-line setting, please provide details of previous treatments in the medication chart above.

Has the patient experienced disease progression following previous treatments? Yes No

Stage III Melanoma – adjuvant treatment – Genetic test results are not required

Has the patient recently undergone complete resection of melanoma with lymph node involvement? Yes No

Please provide the staging of melanoma (ie: 1,2,3, or 4) _____

Please indicate the patient's current ECOG score: _____

Non-small cell lung carcinoma (NSCLC) – Genetic test results are not required

Is Keytruda being used in first-line setting second-line setting other

If being used as second or subsequent line treatment, please provide details of previous treatments in the medication chart above

Will Keytruda be used as:

monotherapy

in combination with

pemetrexed and platinum chemotherapy

carboplatin and either paclitaxel or nab-paclitaxel

other

Is the patient's NSCLC squamous non-squamous

What is the patient's ECOG score? _____

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 the 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: _____

What is the patient's ECOG score: _____

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

Will Keytruda be used as monotherapy? Yes No

Physician's Information (continued) (please print)

Classical Hodgkin Lymphoma – Genetic test results are not required

Has the patient previously received treatment with brentuximab vedotin? Yes No

If yes, please provide details in the treatment chart

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

If yes, please provide details in the treatment chart

If no, is ASCT contraindicated in this patient? Yes No

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

Please select from the following:

Patient has relapsed after an autologous stem cell transplant (ASCT)

Patient is ineligible for ASCT and has received >2 lines of prior therapy

Please ensure treatment chart on page 4 is complete

Will Keytruda be used as monotherapy? Yes No

Microsatellite Instability-High (MSI-H) or mismatch repair deficient (dMMR) cancer - Genetic test results are not required

Please indicate patient's diagnosis:

Colorectal cancer

Endometrial cancer

Has the patient's tumour progressed following previous chemotherapy? Yes No

Please ensure treatment chart on page 4 is complete

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.

Renewal Request – Genetic test results are not required

Start 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 consultations or clinical notes.

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

Off-label use – Genetic test results are not required

Questions 1 – 7 must be completed.

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

Is there 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 alternative 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 efficacy since previous request.

Note for Physician: To be eligible for reimbursement, Great-West Life may require your patient to purchase a drug requiring prior authorization from a pharmacy designated by Great-West 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 Great-West 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 Great-West Life Assurance Company
Drug Services
PO Box 6000
Winnipeg MB R3C 3A5**

**Fax to: The Great-West Life Assurance Company
Fax 1-204-946-7664
Attention: Drug Services**

**Email to: gwldrug.services@gwl.ca
Attention: Drug Services**