

Opdivo (Nivolumab)

The purpose of this form is to obtain the medical information required to assess your request for a drug on the Prior Authorization list under your drug plan benefit coverage. To avoid delays in processing your request, please ensure that all information, including contact information is complete. Completion of this form is not a guarantee of approval. If you have already purchased the drug, please attach all original receipts along with an Extended Health Care Claim form. All costs incurred to complete this form are the plan member's responsibility. If you are registered for the Plan Member Secure Site and have provided an email address, you will receive an email notification when the prior authorization decision is available on your claims statement. If you are not registered on the Plan Member Secure Site, you will be notified of the prior authorization decision by mail.

Important: Please ensure the most current unaltered version of the form is completed and signed. To download the most recent version of the Drug Prior Authorization form go to www.manulife.ca.

1 – Plan member and patient information						To be completed by plan member	
Plan contract number			Plan member certificate number		Plan sponsor		
Plan member name (first)		Plan member name (middle initial)		Plan member name (last)		Plan member Date of birth (dd/mm/yyyy)	
Plan member address (number, street)			Address (suite)		City or town		Province
							Postal code
Patient name (first)		Patient name (middle initial)		Patient name (last)		Patient date of birth (dd/mm/yyyy)	
						Relationship to plan member	
Patient's preferred daytime phone number		Patient's email address (optional)					

1A – Other Group Plan	1B – Recent Coverage Change				
Does the patient have drug coverage under any other group plan? If Yes, please complete below: ☐ Yes ☐ No <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td colspan="2" style="padding: 5px;">Name of insurance company</td> </tr> <tr> <td style="padding: 5px;">Plan contract number</td> <td style="padding: 5px;">Plan member certificate number</td> </tr> </table> Is this drug covered under the other group plan? ☐ Yes ☐ No If no, why was the drug declined by the other group plan? Please attach the other group plan decline notice (typically a letter or statement). We need this decline notice to see if this drug can be approved. If this is a renewal a current decline notice is required.	Name of insurance company		Plan contract number	Plan member certificate number	Did your plan sponsor recently transfer your drug benefits to Manulife? ☐ Yes ☐ No Before joining Manulife, were you receiving coverage for this drug through your previous insurance company? ☐ Yes ☐ No If Yes, attach proof of payment (a copy of a pharmacy receipt showing payment from prior insurance company or an Explanation of Benefits from the prior insurance company). Proceed to section 7.
Name of insurance company					
Plan contract number	Plan member certificate number				

2 – Provincial Plans		To be completed by plan member
Most provinces offer some form of drug coverage to their residents. Your Manulife drug plan supplements the coverage provided by provincial plans. It is important that you or your doctor (if required) apply to the applicable provincial program to ensure there are no delays in your drug reimbursement. Check with your doctor or login to the Manulife Provincial Drug Plans Resource Centre on our Plan Member Secure Site at www.manulife.ca/planmember to confirm if the drug you have been prescribed may be eligible for coverage under a provincial plan. If the drug you have been prescribed is listed under a provincial program, you will need to apply to the program before consideration can be given under your Manulife drug plan.		
Has application been made to the provincial program for coverage? ☐ Yes ☐ No If no, why?		
Has the patient been approved for coverage by the provincial program for this drug? ☐ Yes ☐ No If no, advise why the request was declined?		

In Ontario, for patients that qualify for coverage under the Exceptional Access Program (EAP), if the drug is an EAP drug, a copy of the approval or denial from EAP must be submitted with this form so Manulife can complete the assessment of this request.

3 – Patient Assistance Programs				To be completed by plan member
Have you enrolled in the Patient Assistance Program for the requested drug? ☐ Yes ☐ No If yes, please provide the details below:				
Case Manager Name (first)	Case Manager name (last)	Case Manager Phone	Case Manager Email	
Patient Assistance Program Name				Patient Assistance Program ID Number:

4 – Medical information				To be completed by prescribing physician	
Drug strength and dosage					
Where will treatment be administered?					
☐ Home		☐ MD office		☐ Private Clinic	
		☐ Hospital/In-Patient		☐ Hospital/Out-patient	
Is the MD office located in a hospital?					
				☐ Yes ☐ No	
Will the drug be administered in the MD office or in another area of the hospital? (describe below)					
If the treatment is not being administered at home, please provide:					
Name of private clinic/hospital				Telephone number	
Address (number, street)		Address (suite)	City or town		Province
					Postal code
Please select the diagnosis for which the drug has been prescribed and respond to the corresponding questions.					
☐ Adjuvant treatment of completely resected Melanoma (Stage III/IV)					
Will Opdivo be used as a monotherapy?				☐ Yes ☐ No	
Does the melanoma have regional lymph node involvement or in transit metastases or satellite metastases?				☐ Yes ☐ No	
Are there metastatic nodes or distant metastases present?				☐ Yes ☐ No	
Is there history of ocular/uveal melanoma?				☐ Yes ☐ No	
Note: Approval is limited to 12 months maximum.					
☐ Adjuvant treatment of resected Melanoma (Stage IIB/IIC)					
Will Opdivo be used as a monotherapy?				☐ Yes ☐ No	
Does patient have Stage IIB or IIC melanoma following complete resection?				☐ Yes ☐ No	
Note: Approval is limited to 12 months maximum.					
☐ Unresectable or metastatic Melanoma - Initial Criteria					
Is the patient treatment naïve?				☐ Yes ☐ No	
Will Opdivo be used as monotherapy or in combination with ipilimumab?				☐ Yes ☐ No	
Did patient have prior treatment with ipilimumab in the last 6 months and there is confirmation of disease progression?				☐ Yes ☐ No	
If BRAF V600 mutation is positive, has the patient experienced disease progression following therapy with a BRAF inhibitor?				☐ Yes ☐ No	
Note: Initial and subsequent approvals are limited to 12 months. Additional information is required every 12 months, in order to assess for further coverage.					
☐ Unresectable or metastatic Melanoma - Renewal Criteria					
Is there documented objective evidence of continued benefit for this patient (i.e., absence of disease progression)?				☐ Yes ☐ No	
Is Opdivo used as monotherapy?				☐ Yes ☐ No	

4 – Medical information (continued)	To be completed by prescribing physician
☐ Non-Small Cell Lung Carcinoma (NSCLC) 1st Line Therapy - Initial Criteria	
Is disease metastatic?	☐ Yes ☐ No
Is there EGFR or ALK genomic tumor aberrations?	☐ Yes ☐ No
Has patient received prior systemic therapy for metastatic NSCLC?	☐ Yes ☐ No
Will drug be used in combination with ipilimumab?	☐ Yes ☐ No
Will drug be used in combination with ipilimumab and 2 cycles of platinum-doublet chemotherapy?	☐ Yes ☐ No
Note: Initial and subsequent approvals are limited to 12 months. Additional information is required every 12 months, in order to assess for further coverage.	
☐ Non-Small Cell Lung Carcinoma (NSCLC) 1st Line Therapy - Renewal Criteria	
Is there documented objective evidence of continued benefit for this patient (i.e., absence of disease progression)?	☐ Yes ☐ No
Is drug used in combination with ipilimumab?	☐ Yes ☐ No
Note: Approval is limited to 12 additional months for 24 months maximum.	
☐ Non-Small Cell Lung Carcinoma (NSCLC) 2nd Line Therapy - Initial Criteria	
Will drug be used as monotherapy?	☐ Yes ☐ No
Is disease locally advanced or metastatic?	☐ Yes ☐ No
Has patient had disease progression on or after platinum-containing chemotherapy?	☐ Yes ☐ No
If patient has EGFR or ALK genomic tumour aberrations, has there been disease progression on a therapy for these aberrations?	☐ Yes ☐ No
Note: Initial and subsequent approvals are limited to 12 months. Additional information is required every 12 months, in order to assess for further coverage.	
☐ Non-Small Cell Lung Carcinoma (NSCLC) 2nd Line Therapy - Renewal Criteria	
Is there documented objective evidence of continued benefit for this patient (i.e., absence of disease progression)?	☐ Yes ☐ No
Is drug used as monotherapy?	☐ Yes ☐ No
Note: Initial and subsequent approvals are limited to 12 months. Additional information is required every 12 months, in order to assess for further coverage.	
☐ Resectable Non-Small Cell Lung Cancer (NSCLC)	
Will drug be used in combination with platinum-doublet chemotherapy in the neoadjuvant setting?	☐ Yes ☐ No
Does patient exhibit tumours $\geq$ 4 cm or node positive?	☐ Yes ☐ No
Note: Approval is limited to 3 cycles only.	
☐ Malignant Pleural Mesothelioma (MPM) - Initial Criteria	
Does patient have unresectable MPM?	☐ Yes ☐ No
Has patient received prior systemic therapy for MPM?	☐ Yes ☐ No
Will drug be used in combination with ipilimumab?	☐ Yes ☐ No
Note: Initial and subsequent approvals are limited to 12 months. Additional information is required every 12 months, in order to assess for further coverage. Maximum treatment duration is 24 months.	
☐ Malignant Pleural Mesothelioma (MPM) - Renewal Criteria	
Is there documented objective evidence of continued benefit for this patient (i.e., absence of disease progression)?	☐ Yes ☐ No
Is drug being used in combination with ipilimumab?	☐ Yes ☐ No

4 – Medical information (continued)		To be completed by prescribing physician	
☐ Advanced or metastatic Renal Cell Carcinoma (RCC) - Initial Criteria			
Is drug being used as monotherapy after receiving prior anti-angiogenic therapy?	☐ Yes	☐ No	
Is drug being used in combination with ipilimumab for a patient with intermediate/poor-risk RCC?	☐ Yes	☐ No	
Is drug being used in combination with cabozantinib for previously untreated RCC?	☐ Yes	☐ No	
Note: Initial and subsequent approvals are limited to 12 months. Additional information is required every 12 months, in order to assess for further coverage. If drug is being used in combination with cabozantinib, maximum treatment duration is 24 months.			
☐ Advanced or metastatic Renal Cell Carcinoma (RCC) - Renewal Criteria			
Is there documented objective evidence of continued benefit for this patient (i.e., absence of disease progression)?	☐ Yes	☐ No	
Is drug used as monotherapy?	☐ Yes	☐ No	
Is drug used in combination with cabozantinib?	☐ Yes	☐ No	
☐ Recurrent or metastatic Squamous Cell Carcinoma of the head and neck (SCCHN) - Initial Criteria			
Has the patient progressed on or after platinum-based therapy?	☐ Yes	☐ No	
Will drug be used as monotherapy?	☐ Yes	☐ No	
Note: Initial and subsequent approvals are limited to 12 months. Additional information is required every 12 months, in order to assess for further coverage.			
☐ Recurrent or metastatic Squamous Cell Carcinoma of the head and neck (SCCHN) - Renewal Criteria			
Is there documented objective evidence of continued benefit for this patient (i.e., absence of disease progression)?	☐ Yes	☐ No	
Is Opdivo used as monotherapy?	☐ Yes	☐ No	
☐ Classical Hodgkin Lymphoma (cHL) - Initial Criteria			
Will drug be used as monotherapy?	☐ Yes	☐ No	
Patient has relapsed or progressed after autologous stem cell transplant (ASCT) and brentuximab vedotin?	☐ Yes	☐ No	
Patient has relapsed or progressed after 3 or more lines systemic therapy including ASCT?	☐ Yes	☐ No	
Will drug be used in combination with doxorubicin, vinblastine, and dacarbazine (N+AVD) as primary systemic therapy?	☐ Yes	☐ No	
Note: Approvals for prior authorization drugs may be subject to a time limitation. If applicable, you will be required to provide additional information to Manulife to assess continued coverage. You will be advised of the approval duration at the time of approval.			
☐ Classical Hodgkin Lymphoma (cHL) - Renewal Criteria			
Is there documented objective evidence of continued benefit for this patient (i.e., absence of disease progression)?	☐ Yes	☐ No	
Is drug used as monotherapy?	☐ Yes	☐ No	
☐ Hepatocellular Carcinoma (HCC) - Renewal Criteria Only			
Is there documented objective evidence of continued benefit for this patient (i.e., absence of disease progression)?	☐ Yes	☐ No	
Is drug used as monotherapy?	☐ Yes	☐ No	
Note: Renewal approvals are limited to 12 months. Additional information is required every 12 months in order to assess for further coverage.			

4 – Medical information (continued)	To be completed by prescribing physician
☐ Metastatic Colorectal Cancer (MCC) - Initial Criteria	
Is the drug being taken in combination with ipilimumab?	☐ Yes ☐ No
Does the patient have microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)?	☐ Yes ☐ No
Has the patient tried prior fluoropyrimidine-based therapy in combination with oxaliplatin or irinotecan?	☐ Yes ☐ No
Note: Initial and subsequent approvals are limited to 12 months. Additional information is required every 12 months, in order to assess for further coverage.	
☐ Metastatic Colorectal Cancer (MCC) - Renewal Criteria	
Is there documented objective evidence of continued benefit for this patient (i.e., absence of disease progression)?	☐ Yes ☐ No
Is drug used as monotherapy?	☐ Yes ☐ No
☐ Adjunctive treatment of completely resected Esophageal or Gastroesophageal Junction (GEJ) cancer - Initial Criteria	
Will drug be used as monotherapy?	☐ Yes ☐ No
Does the patient have residual pathologic disease following neoadjuvant chemoradiotherapy (CRT)?	☐ Yes ☐ No
Note: Initial approval is limited to 6 months. Additional information is required after 6 months, in order to assess for further coverage. Maximum treatment duration is 12 months.	
☐ Adjunctive treatment of completely resected Esophageal or Gastroesophageal Junction (GEJ) cancer - Renewal Criteria	
Is there documented objective evidence of continued benefit for this patient (i.e., absence of disease progression)?	☐ Yes ☐ No
Is drug used as monotherapy?	☐ Yes ☐ No
☐ HER2 negative advanced or metastatic Gastric Cancer (GC), Gastroesophageal Junction (GEJ) cancer or Esophageal Adenocarcinoma (EAC) - Initial Criteria	
Will drug be given in combination with fluoropyrimidine and platinum containing chemotherapy?	☐ Yes ☐ No
Does patient have previously untreated metastatic gastric cancer (GC), gastroesophageal junction cancer (GEJC), or esophageal adenocarcinoma (EAC)?	☐ Yes ☐ No
Note: Initial approval is limited to 6 months. Additional information is required after 6 months, in order to assess for further coverage. Maximum treatment duration is 24 months.	
☐ HER2 negative advanced or metastatic Gastric Cancer (GC), Gastroesophageal Junction (GEJ) cancer or Esophageal Adenocarcinoma (EAC) - Renewal Criteria	
Is there documented objective evidence of continued benefit for this patient (i.e., absence of disease progression)?	☐ Yes ☐ No
Note: Approval is limited to 18 additional months for 24 months maximum.	
☐ Unresectable or metastatic Esophageal Squamous Cell Carcinoma (ESCC) - Initial Criteria	
Does patient's tumour have cell PD-L1 expression $\geq$ 1% determined by a validated test?	☐ Yes ☐ No
Has patient received prior systemic therapy for metastatic ESCC?	☐ Yes ☐ No
Will drug be used in combination with ipilimumab?	☐ Yes ☐ No
Will drug be used in combination with fluoropyrimidine- and platinum-containing chemotherapy?	☐ Yes ☐ No
Note: Initial approval is limited to 12 months. Additional information is required after 12 months, in order to assess for further coverage. Maximum treatment duration is 24 months.	
☐ Unresectable or metastatic Esophageal Squamous Cell Carcinoma (ESCC) - Renewal Criteria	
Is there documented objective evidence of continued benefit for this patient (i.e., absence of disease progression)?	☐ Yes ☐ No
Is drug taken in combination with ipilimumab?	☐ Yes ☐ No
Is drug taken in combination with fluoropyrimidine- and platinum-containing chemotherapy?	☐ Yes ☐ No

4 – Medical information (continued)	To be completed by prescribing physician
☐ Any other diagnosis	
Please provide the specific diagnosis and any Canadian clinical research that supports the use of this drug in your patient's context.	

5 – Drug history			To be completed by prescribing physician
If no previous therapies have been tried for the selected diagnosis, please specify the rationale: ☐ Risk of drug interaction ☐ Patient has contraindication ☐ Other			
Please provide medical rationale			
For the selected diagnosis, please provide all previous and current drug therapies in the area below:			
Drug name	Start date (yyyy/mmm)	End date (yyyy/mmm)	Specify Outcome: ☐ Intolerance (Allergy/Adverse Event) ☐ Inadequate/Suboptimal Response
Will the patient be continuing this medication in addition to new therapy?			☐ Yes ☐ No
Drug name	Start date (yyyy/mmm)	End date (yyyy/mmm)	Specify Outcome: ☐ Intolerance (Allergy/Adverse Event) ☐ Inadequate/Suboptimal Response
Will the patient be continuing this medication in addition to new therapy?			☐ Yes ☐ No
Drug name	Start date (yyyy/mmm)	End date (yyyy/mmm)	Specify Outcome: ☐ Intolerance (Allergy/Adverse Event) ☐ Inadequate/Suboptimal Response
Will the patient be continuing this medication in addition to new therapy?			☐ Yes ☐ No
Drug name	Start date (yyyy/mmm)	End date (yyyy/mmm)	Specify Outcome: ☐ Intolerance (Allergy/Adverse Event) ☐ Inadequate/Suboptimal Response
Will the patient be continuing this medication in addition to new therapy?			☐ Yes ☐ No
6 – Physician information			To be completed by prescribing physician
Prescribing physician's name (first)	Prescribing physician's name (last)	College/License Number	Specialty
Address (number, street)			Address (suite)
City or town	Province	Postal code	
Telephone number	Extension	Fax number	
Physician authorization			
I certify that the information in this form is true and complete to the best of my knowledge. The information in this statement will be kept in a Group Benefits health file with Manulife and might be accessible by the patient or third parties to whom access has been granted or those authorized by law. By providing the information, I consent to such unedited release of any information contained herein.			
Physician Signature			Date (dd/mmm/yyyy)

I certify that I, my spouse and/or my dependents of minor or major age ("Dependents") require the drug named on this form (or an equivalent drug that Manulife proposes).

I authorize:

Manulife and/or its service providers, its reinsurers, and their service providers to collect, use, maintain and disclose my personal information related to this application ("Personal Information") for the purposes of:

- The assessment of the drug authorization request
- Managing my Group Benefits plan
- Assessing and processing claims
- Auditing and investigation of claims
- Patient assistance programs, if applicable
- And/or other purposes identified in the Personal Information Statement for Employers' Group Benefits plans (collectively, the "Purposes").

Any person or organization who has Personal Information about me that is required for Manulife to assess this drug authorization request, including any medical and health care professionals, institution, pharmacy or any other medical or health care related facility, professional regulatory bodies, any employer, group plan administrator, insurer, investigative agency, and any other administrators of other benefits programs to collect, use, maintain, disclose and exchange this information with each other and with Manulife, its reinsurers and/or its service providers, for the Purposes.

I understand:

- A Manulife approved pharmacy vendor may engage me in the capacity of case management to provide support as part of this program. I acknowledge that participation in this program is entirely voluntary. My decision to participate will not have any impact on the assessment of my claim.
- If my Manulife plan recommends purchasing a drug that requires prior authorization from a preferred pharmacy or provider, a case manager may contact me, my doctor and/or patient assistance program to arrange to have my prescription(s) transferred to the preferred pharmacy or provider.
- That except where there are contractual restrictions, Manulife employees, authorized organizations, service providers and reinsurers are located both within Canada and outside of Canada. Therefore, my Personal Information may be subject to interprovincial or cross-border transfers for the Purposes and may be subject to the laws of those jurisdictions.
- I may withdraw my consent for certain uses of my Personal Information, subject to legal and contractual restrictions. If I do so, Manulife may treat my withdrawal of consent as a request to dismiss, rescind or terminate my claim.

I agree:

- A photocopy or electronic version of this consent is valid.
- I have the right to access and verify my Personal Information maintained in Manulife's files and to request any factually inaccurate Personal Information be corrected, if appropriate.
- Requests can be sent to: Privacy Officer Manulife, P.O. Box 1602, Del Stn 500-4-A, Waterloo, Ontario N2J 4C6 or Canada_Privacy@manulife.ca
- For more information, I can review the [Personal Information Statement for Employers' Group Benefits Plans](#) and the [Canadian Privacy Policy](#).

I confirm that:

- The information I have given in this request is true and accurate.
- By signing, I give permission to and/or confirm that I have obtained the individual's consent for the collection, use, disclosure or otherwise processing of the individual's Personal Information for the Purposes (as these terms are defined above).

Plan member's signature

Date signed (dd/mm/yyyy)

Protecting your personal information is important to us. People who can see your personal information are:

- Manulife employees who need to see your information to do their jobs.
- People you've given permission to.

To find out more about Manulife's privacy policy please see manulife.ca

8 – Submission instructions

Plan Member Secure Site

1. Log in to the **Plan Member Secure Site**.
2. Choose **“Claims”**
3. Go to **“Submit a Claim.”**
4. Under **Service Provider**, select **“Other.”**
5. Choose **“Estimate”** as the **Claim Type**.

Mobile App Site

1. Open the **Mobile Site** on your device.
2. Select **“Submit a Claim.”**
3. Choose **“Estimate”** as the **Claim Type**.

Mail or fax

If you live in Quebec:

Manulife Group Benefits Health Claims
Attention Prior Authorization Team
PO BOX 2580, STATION B
MONTREAL QC H3B 5C6

Fax: 1-855-752-0404

If you live outside Quebec:

Manulife Group Benefits Health Claims
Attention Prior Authorization Team
PO BOX 1653
WATERLOO ON N2J 4W1

Fax: 1-855-752-0404

Please retain a photocopy for your files.

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