

### **KEYTRUDA** PRIOR APPROVAL REQUEST

Send completed form to: Service Benefit Plan **Prior Approval** P.O. Box 52080 MC 139 Phoenix, AZ 85072-2080 **Attn. Clinical Services** Fax: 1-877-378-4727

Federal Employee Program. Additional information is required to process your claim for prescription drugs. Please complete the patient portion, and have the prescribing physician complete the physician portion and submit this completed form.

Patient Information (required)		Provider Information (required)							
Date:					Provider Name:				
Patient Name:					Specialty:		NPI:		
Date of Birth: Sex: □Male □Female			Office Phone:		Office Fax:				
Street Address:					Office Street Address:				
City:		State:	Zip:		City:	St	ate:	Zip:	
Patient ID: <b>R</b>	l I	1 1 1	i i		Physician Signature:			•	
	,		PHYSICIA	N C	COMPLETES				
•	nt been on this me	NOTE: For	m must be comp nuously for the	firm v pletectast (	embrolizumab) which medication is part of to d in its entirety for proc months excluding san	cessing	ease select an	swer belo	w:
	is a PA renewal s <b>INITIATION</b>				please answer the ques	tions on <u>F</u>	PAGE 6		
	t for brand or gen			quest	ions below.				
3. Does the pres	criber agree to di	scontinue treat	ment for any in		ne mediated adverse readssion?  \( \textstyle \textstyl	ction (enc	ephalitis, nep	hritis, rash	1,
	atient: Is the patie	•	,	_					
	vill the patient be	-	-		ion during treatment wit	:h Keytru	da and for 4 n	nonths aft	er the last
□Biliary trace a. Is the ca b. Will thi □Bladder can a. Does th *If Y b. Was the c. Is the p d. Is the p  *If Y □Breast can a. Does th □Yes: □No: F	e patient have a ce ES, is the cancer the cancer responsivation considered attent eligible to the ES, has the patient the patient have high Will Keytruda be *If NO, will Keylease answer the	anced unresect used in combinution of the combinuti	n-muscle invasinoma in situ? Calmette-Guerin Yes No etomy? Yes* to undergo cyste age triple-negationation with che das a single agstions:	ive by Ye n (BC	ine and cisplatin? □Ye ladder cancer (NMIBC) s □No CG)? □Yes □No lNo ay? □Yes □No oreast cancer (TNBC)? Inerapy as neoadjuvant tr fter surgery as adjuvant	? □Yes*  Please self eatment?  treatment	ect answer be □Yes □No t? □Yes □	o* No	
ii ii □Cutaneous	i. Will Keytruda lii. Does the patien *If YES, does squamous cell ca	be used in com nt have a PD-L es the patient h rcinoma (cSCO	bination with classification with classification with classification with the classification with the classification with clas	hemo sion l posi	e or metastatic triple-ne, otherapy? □Yes □No determined by an FDA-itive score (CPS) of greaterally advanced? □Yes	approved	test? □Yes*	· □No	No □No
-	atient's cancer cu				•	, 💷110			

#### PLEASE PROCEED TO PAGE 2 FOR ADDITIONAL DIAGNOSES

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## KEYTRUDA PRIOR APPROVAL REQUEST

**PAGE 2 – PHYSICIAN COMPLETES** 

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Patient Name:	DOB:	Patient ID: R
☐Esophageal or gastroesopha		
	locally advanced or metastatic? $\Box$ Y	
	ble to surgical resection or definitive	
	n combination with platinum- and flunt have a PD-L1 tumor expression?	oropyrimidine-based chemotherapy? □Yes* □No □Yes* □No
*If YES, does the pa	atient have a combined positive score	e (CPS) greater than or equal to 1? \(\sigma\)Yes \(\sigma\)No
		lines of systemic therapy? □Yes* □No
	nt have tumors of squamous cell hist o 10 as determined by an FDA-appro	ology that express PD-L1 with combined positive score (CPS) oved test? □Yes □No
□Cervical cancer		
	to be persistent, recurrent, or metasta	atic? Please select answer below:
☐ <b>Yes</b> : Please answer the	- ·	
	or Recurrent: Please answer the foll	<b>U</b> 1
	truda be used as a single agent? $\Box Y$	
· · · · · · · · · · · · · · · · · · ·	atient had disease progression on or a	* *
<u> </u>	be used in combination with chemo	± 7
* <i>If YES</i> , do	oes the patient have a combined posi-	letermined by an FDA-approved test? □Yes* □No tive score (CPS) greater than or equal to 1? □Yes □No
□ <b>No</b> : Please the answer		
<u> -</u>	nt have FIGO 2014 Stage III-IVA cer	
· · · · · · · · · · · · · · · · · · ·	be used in combination with chemo	radiotherapy? \(\superscript{Yes}\) \(\superscript{UNo}\)
☐ Endometrial carcinoma		
		ent endometrial carcinoma? Please select answer below:
	netrial carcinoma: Please answer the	
_	candidate for curative surgery or rad	
<u>-</u>		prior systemic therapy?  \( \textstyle \text
		ient (dMMR) as determined by an FDA approved test?  tus microsatellite instability-high (MSI-H) as determined by an  No
iv. If dMMR or	MSI-H: Will Keytruda be used as a	
v. <b>If NOT dMM</b>	· ·	status mismatch repair proficient (pMMR) as determined by an
	a be used in combination with Lenvir	ma (lenvatinib)? □Yes □No
		noma: Please answer the following question:
i. Will Keytruda agent? □Yes		atin and paclitaxel, followed by Keytruda as a single
□No, the patient does r	not have advanced, primary advan	ced, or recurrent endometrial carcinoma.
☐Gastric or gastroesophageal	junction adenocarcinoma	
a. Is the cancer locally adva	nnced unresectable <b>OR</b> metastatic?	⊒Yes □No
b. Will Keytruda be used as	s first-line treatment? □Yes □No	
c. Does the patient have a P	PD-L1 tumor expression determined by	by an FDA-approved test? □Yes* □No
*If YES, does the patien	nt have a combined positive score (C	PS) greater than or equal to 1? □Yes □No
d. Is the cancer HER2-posit	tive? Please select answer below:	
☐Yes: Please answer the	e following question:	
	be used in combination with trastuzu ? □Yes □No	imab, fluoropyrimidine- and platinum-containing
□ <b>No</b> : Please answer the	following question:	
i. Will Keytruda □Yes □No	<u> </u>	yrimidine- and platinum-containing chemotherapy?



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PAGE 3 - PHYSICIAN COMPLETES					
Patient Name: DOB: Patient ID: R					
□Head and Neck Squamous Cell Carcinoma (HNSCC)  a. Is the patient's cancer considered recurrent or metastatic? □Yes □No  b. Has the patient experienced disease progression on or after platinum-containing chemotherapy? □Yes* □No  *If YES, will Keytruda be used as a single agent? □Yes □No					
c. Does the patient have a PD-L1 tumor expression determined by an FDA-approved test? □Yes* □No *If YES, does the patient have a combined positive score (CPS) of greater than or equal to 1? □Yes □No d. Will Keytruda be used as a single agent for first-line treatment? □Yes □No					
e. Will Keytruda be used in combination with platinum and fluorouracil (FU) as a first-line treatment? □Yes □No □Hepatocellular carcinoma (HCC) a. Is the hepatocellular carcinoma (HCC) secondary to hepatitis B? □Yes □No					
b. Has the patient received prior systemic therapy other than a PD-1/PD-L1-containing regimen?   No  Hodgkin lymphoma					
a. Does the patient have refractory or relapsed classical Hodgkin lymphoma (cHL)? □Refractory □Relapsed □No b. <b>If Relapsed</b> : Has the patient relapsed after 2 or more lines of therapy? □Yes □No					
□Malignant pleural mesothelioma (MPM)  a. Does the patient have unresectable advanced or metastatic malignant pleural mesothelioma (MPM)? □Yes  b. Will this medication be used in combination with pemetrexed and platinum chemotherapy as first-line treatment? □Yes □No					
□Melanoma a. Does the patient have a diagnosis of unresectable or metastatic melanoma? □Yes □No*  *If NO, please answer the following questions: i. Does the patient have stage IIB, IIC, or III melanoma? □Yes □No ii. Has the patient undergone a complete resection? □Yes □No iii. Will Keytruda be used as adjuvant treatment? □Yes □No					
□Merkel cell carcinoma (MCC) a. Is the cancer considered locally advanced or metastatic? □Yes* □No *If YES, is the cancer recurrent? □Yes □No					
□Microsatellite instability-high (MSI-H) colorectal cancer OR □Mismatch repair deficient (dMMR) colorectal cancer a. Is the patient's cancer considered unresectable or metastatic? □Yes □No b. Was the patient's tumor status determined by an FDA approved test? □Yes □No					
□Microsatellite instability-high (MSI-H) solid tumors					
□Primary mediastinal large B-cell lymphoma (PMBCL) a. Does the patient have a diagnosis of refractory primary mediastinal large B-cell lymphoma (PMBCL)? □Yes b. Has the patient relapsed after 2 or more prior lines of therapy? □Yes □No					
□Renal cell carcinoma (RCC)  a. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC)? □Yes □No					
b. Will Keytruda be used as first-line treatment or adjuvant treatment? <i>Please select answer below:</i> \[ \textstyle \tex					
□ <b>First-line treatment</b> : Please answer the following questions:  i. Does the prescriber agree to monitor for hepatotoxicity? □ Yes □ No					
ii. Will Keytruda be used in combination with Inlyta (axitinib) or Lenvima (lenvatinib)?   Yes   No					

PLEASE PROCEED TO PAGE 4 FOR ADDITIONAL DIAGNOSES

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physician portion and submit this completed form.

KEYTRUDA
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PAGE 4 - PHYSICIAN COMPLETES				
Patient Name:	DOB:	Patient ID: R		
□Tumor mutational burden-high (TMB-H)	solid tumors			

☐Tumor mutational burden-high (TMB-H) solid tumors
a. Are the patient's tumors considered unresectable or metastatic? □Yes □No
b. Is the patient a pediatric patient with TMB-H central nervous system cancer? □Yes □No
c. Does the patient have more than or equal to 10 mutations/megabase (mut/Mb) solid tumors, as determined by an FDA approved test? □Yes □No
d. Has the patient had disease progression following prior treatment? □Yes □No
e. Does the patient have satisfactory alternative treatment options? ☐Yes ☐No
□ Urothelial carcinoma a. Does the patient have a diagnosis of locally advanced or metastatic urothelial carcinoma? □ Yes □ No

b.	Will Keytruda be used in combination with Padcev (enfortumab vedotin)?	' ⊔Yes	⊔No
c.	s the patient eligible for any platinum-containing chemotherapy? \(\sigma\)Yes	□No	

- d. Has the patient had disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy? □Yes □No
- e. Will Keytruda be used to used in as a single agent? □Yes □No

## Non-small cell lung cancer (NSCLC)

a. Does the patient have metastatic non-small cell lung cancer? *Please select answer below:* 

□Yes: Is the non-small cell lung cancer considered either squamous or nonsquamous? *Please select answer below:* 

☐Yes: Please select answer below:

□Nonsquamous: Please answer the following questions:

i. Will Keytruda be used in combination with pemetrexed (Alimta) and platinum chemotherapy as a first

line treatment?  $\square$ Yes  $\square$ No ii. Is the patient negative for EGFR or ALK tumor expression?  $\square$ Yes  $\square$ No

□Squamous: Will Keytruda be used in combination with carboplatin and either paclitaxel or nab-paclitaxel as a first line treatment? □Yes □No

□**No**: Please answer the following questions:

i. Will Keytruda be used as a single agent? □Yes □No

ii. What is the patient's Tumor Proportion Score (TPS) as determined by an FDA-approved PD-L1 tumor expression test? \_\_\_\_\_\_ % □Patient has not been tested

iii. Has the patient had lab tests to determine if there is EGFR and/or ALK tumor expression? □Yes\* □No \*If YES, what were the results of the test? Please select answer below:

□Negative: Did the patient have disease progression on or after a platinum-containing chemotherapy? □Yes □No\*

\**If NO*, will Keytruda be used as first line treatment? □Yes □No □**Positive**: Has the patient had disease progression after a targeted FDA-approved therapy? □Yes □N

□No: Does the patient have resectable (tumors greater than or equal to 4cm or node positive) NSCLC? *Select answer below:* 

**Yes**: Please answer the following questions:

i. Will Keytruda be used as neoadjuvant treatment? □Yes □No

ii. Will Keytruda be used in combination with platinum-containing chemotherapy? □Yes □No

iii. Will Keytruda be used in a single agent after resection? □Yes □No

□No: Which stage of non-small cell lung cancer does the patient have? *Please select answer below:* 

**□Stage IA** 

□Stage IB (T2a greater than or equal to 4cm) <u>OR</u> □Stage IIA or IIB

i. Will Keytruda be used as a single agent? □Yes □No

ii. Will Keytruda be used as adjuvant treatment following resection and platinum-based chemotherapy? ☐Yes ☐No

PLEASE PROCEED TO PAGE 5 FOR ADDITIONAL NSCLC STAGES AND DIAGNOSES

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**Patient** 

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atient Name:	PAGE 5 - PHYSICIAN COMPLETES  DOB: Patient ID: R
	□Stage IIIA: Is Keytruda being used as first-line treatment or adjuvant treatment? <i>Please select answer below:</i> □Adjuvant treatment: Will Keytruda be used as a single agent? □Yes* □No *If YES, will Keytruda be used as adjuvant treatment following resection and platinum-based chemotherapy? □Yes □No
	□ <b>First-line treatment:</b> Please answer the following questions:  i. Is the patient a candidate for surgical resection or definitive chemoradiation? □ Yes □ No
	ii. What is the patient's Tumor Proportion Score (TPS) as determined by an FDA-approved PD-L1 tumor expression test? % □Patient has not been tested
	iii. Is the patient negative for EGFR or ALK tumor aberrations? □Yes □No
	iv. Will Keytruda be used as a single agent for first line treatment? □Yes □No
	□No (please specify):
	□Stage IIIB or IIIC: Please answer the following questions:
	i. Is the patient a candidate for surgical resection or definitive chemoradiation? $\square$ Yes $\square$ No
	ii. What is the patient's Tumor Proportion Score (TPS) as determined by an FDA-approved PD-L1 tumor expression test? %   □Patient has not been tested
	iii. Is the patient negative for EGFR or ALK tumor aberrations? □Yes □No
	iv. Will Keytruda be used as a single agent for first line treatment? □Yes □No
	□Stage IV: Is the non-small cell lung cancer considered either squamous or nonsquamous? <i>Select answer below:</i> □Nonsquamous: Please answer the following questions:
	<ul> <li>i. Will Keytruda be used in combination with pemetrexed (Alimta) and platinum chemotherapy as a first line treatment? □Yes □No</li> </ul>
	ii. Is the patient negative for EGFR or ALK tumor expression? □Yes □No
	□Squamous: Will Keytruda be used in combination with carboplatin and either paclitaxel or nab-paclitaxel as a first line treatment? □Yes □No
	□ <b>No</b> : Please answer the following questions:  i. Will Keytruda be used as a single agent? □Yes □No
	ii. What is the patient's Tumor Proportion Score (TPS) as determined by an FDA-approved PD-L1 tumor expression test?
	iii. Has the patient had lab tests to determine if there is EGFR and/or ALK tumor expression? □Yes □No
	*If YES, what were the results of the test? Please select answer below:
	□Negative: Did the patient have disease progression on or after a platinum-containing chemotherapy? □Yes □No*
	* $If NO$ , will Keytruda be used as first line treatment? $\square$ Yes $\square$ No
	□ <b>Positive</b> : Has the patient had disease progression after a targeted FDA-approved therapy? □Yes □No
□Other diagnos	is (please specify):

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Patient Inform	ation (required)		Prov	ider Informatio	ON (required)
Date:			Provider Name:		
Patient Name:			Specialty:	NPI:	
Date of Birth: Sex: □Male □Female			Office Phone:	Office	Fax:
Street Address:			Office Street Address:		
City:	State:	Zip:	City: State: Zip:		
Patient ID:			Physician Signature:		
R	<u> </u>	PHYSICIAN	COMPLETES		
CO			ERAPY (PA RI	ENIEWAI)	
	www.fepblue.org/for NOTE: Form in dication continuo of therapy, please for CONTINUATE or CONTINUATE	Keytruda (primulary to confirm nust be completed outly for the last answer the quest filon of therapy Generic int for any immular disease progrese potential? The potential? The potential? The potential? The potential ion with gemeitant ion with gemeitant in the potential ion with gemeitant in the potential ion with gemeitant ion with gemeitant in the potential in the potential ion with gemeitant ion with gemeitant in the potential in the potential in the potential ion with gemeitant in the potential in th	embrolizumab) which medication is part of ed in its entirety for proceed from the excluding sations on PAGE 1 r, please answer the questions on PAGE 1 replace answer the questions on PAGE 1 replace answer the questions of PAGE 1 replace answer the ques	f the patient's benefit occassing amples? Please selections below: action (encephalitis with Keytruda and for Yes  No	or 4 months after the last
□ Breast cancer  a. Does the patient have hi □ Yes: Will Keytruda be □ No: Does the patient h  *If YES, will Ke □ Cervical cancer  a. Is the cancer considered  *If NO, does the patie □ Cutaneous squamous cell can  a. Is the patient's cancer con □ Endometrial carcinoma	gh-risk early-stage used as a single have locally recurrently to be persistent, and to be persistent, and the persistent have FIGO 20 recinoma (cSCC) considered recurrently	ge triple-negative agent as adjuvant rent unresectable combination we recurrent, or me 14 Stage III-IVA	e breast cancer (TNBC) nt treatment? □Yes □ e or metastatic triple-ne ith chemotherapy? □Y tastatic? □Metastatic A cervical cancer? □Ye clocally advanced? □Ye	INo egative breast cance Yes □No □Persistent □ es □No Yes □No	er? □Yes* □No □Recurrent □No*
* <i>If NO</i> , will □ <b>Yes, primary advar</b>	ometrial carcinon a be used as a sin l Keytruda be use	ma: Please answ gle agent? \(\sigma\)Ye d in combination t endometrial c	er the following questices \(\textsq\)No*  In with Lenvima (lenvation arcinoma: Please answ	ons: inib)? □Yes □N	No
□No. the natient does	anot have advan	ced nrimary a	dvanced, or recurrent	endometrial carci	noma



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**KEYTRUDA** 

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### **PAGE 7 – PHYSICIAN COMPLETES**

Patient Name:	DOB:	Patient ID: R
☐Esophageal or gastroesophage a. Is the cancer considered l	eal junction carcinoma ocally advanced or metastatic?   Yes	₃ □No
☐ Hepatocellular carcinoma (HC☐ Head and neck squamous cell	CC)	
☐Hodgkin lymphoma		
a. Does the patient have ref	ractory or relapsed classical Hodgkin ly	ymphoma (cHL)? □Refractory □Relapsed □No
☐Gastric or gastroesophageal ju a. Is the cancer HER2-positiv	nnction adenocarcinoma we? Please select answer below:	
	ally advanced unresectable <b>OR</b> metastate used in combination with trastuzuma	atic? □Yes □No ab, fluoropyrimidine- and platinum-containing
	lly advanced unresectable <b>OR</b> metastate used in combination with fluoropyrim	
☐ Malignant pleural mesothelion a. Does the patient have unre		nant pleural mesothelioma (MPM)? □Yes □No
*If NO, please answer the i. Does the patient has	ve stage IIB, IIC, or III melanoma? $\Box$	lYes □No
ii. Has the patient un	dergone a complete resection? □Yes	□No
■ Merkel cell carcinoma (MCC)  a. Is the cancer considered 1  *If YES, is the cancer 1	ocally advanced or metastatic? □Yes*	* □No
☐Microsatellite instability-high a. Is the patient's cancer con	(MSI-H) colorectal cancer <u>OR</u> unsidered unresectable or metastatic?	☐Mismatch repair deficient (dMMR) colorectal cancer☐Yes ☐No
☐Microsatellite instability-high a. Are the patient's tumors of	(MSI-H) solid tumors <u>OR</u> □Mi considered unresectable or metastatic?	ismatch repair deficient (dMMR) solid tumors  ☐Yes ☐No
□Non-small cell lung cancer (N a. Does the patient have me	ISCLC) tastatic non-small cell lung cancer? <b>Ple</b>	ease select answer below:
□ <b>Yes</b> : Is the NSCLC cor	nsidered either squamous or nonsquamo	ous? □Nonsquamous □Squamous □No
*	ave resectable (tumors greater than or e tage of NSCLC does the patient have?	equal to 4cm or node positive) NSCLC?  Yes No*  *Please select answer below:
□Stage IA □ □Stage IIIB or	IStage IB (T2a greater than or equal IIIC	al to 4cm) □Stage IIA or IIB □Stage IIIA
□Stage IV: Is the	ne NSCLC considered either squamous	s or nonsquamous? □Nonsquamous □Squamous □No
☐Primary mediastinal large B-c a. Does the patient have a d	ell lymphoma (PMBCL) iagnosis of refractory primary mediasti	inal large B-cell lymphoma? □Yes □No

### PLEASE PROCEED TO PAGE 8 FOR ADDITIONAL DIAGNOSES



# BlueShield. KEYTRUDA Federal Employee Program. PRIOR APPROVAL REQUEST

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Patient Name:	DOB:	Patient ID: R	
□Renal cell carcinoma (RCC)	lia-masia of advanced usual cell cell		
-	liagnosis of advanced renal cell car s first-line treatment or adjuvant tre		☐First-line treatment
c. <b>If First-Line Treatment</b> i. Does the prescriber a	t: Please answer the following ques agree to monitor for hepatotoxicity's and in combination with Inlyta (axit	stions: ? □Yes □No	
☐Tumor mutational burden-hig a. Are the patient's tumors	th (TMB-H) solid tumors considered unresectable or metasta	tic? □Yes □No	
b. Is the patient a pediatric	patient with TMB-H central nervoo	us system cancer? □Yes □N	0
☐Urothelial carcinoma			
a. Does the patient have a c	liagnosis of locally advanced or me	etastatic urothelial carcinoma?	□Yes □No
•	a combination with Padcev (enfortube used as a single agent?   Yes		
□Other diagnosis (please speci	fy):		

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