SA2498 - Pembrolizumab

APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

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APPLICANT (stamp or sticker acceptable)	PATIENT NHI:	REFERRER Reg No:
Reg No:	First Names:	First Names:
Name:	Surname:	Surname:
Address:	DOB:	Address:
	Address:	
Fax Number:		Fax Number:
Pembrolizumab		
Prerequisites (tick boxes where appropriate) The individual is currently on treatmor The individual has resectable and The individual has not receive melanoma and Treatment must be prior to come and Pembrolizumab must be adme and The individual has ECOG pereceived and The individual has ECOG pereceived and	ninistered as monotherapy	ia prior to commencing treatment al) (see note) re setting for their stage IIIB, IIIC, IIID or IV

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Reg No:			First Names:	First Names:	
Name	e:			Surname:	Surname:
Addre	ess:			DOB:	Address:
				Address:	
Fax N	lumbe	r:			Fax Number:
Pem	broli	zumab	- continued		
Ren	ewal -	– stage II	or IV resectable melanom	a - neoadjuvant	
O		mana I Nivo			
	-		mber (if known):		
		-	n a reievant specialist or any oxes where appropriate)	relevant practitioner on the recommendation of a rele	vant specialist. Approvals valid for 4 months.
	_				
			The individual has received	neoadjuvant treatment with an immune checkpoint in	hibitor
		and		,	
			The individual meets initial	application criteria for pembrolizumab for stage III or I	V resected melanoma – adjuvant
	or				
		The individual has received	neoadjuvant and adjuvant treatment with an immune	checkpoint inhibitor	
		and	-		
			The individual meets renew	ral criteria for pembrolizumab for stage III or IV resecte	ed melanoma – adjuvant
	or				
		<u></u>	The individual has received	neoadjuvant and adjuvant treatment with an immune	checkpoint inhibitor
		and	The individual has metasta	tic or unresectable melanoma (excluding uveal) stage	III or IV
		and			
			The individual meets initial	application criteria for pembrolizumab for unresectable	e or metastatic melanoma
	or				
			The individual has received	neoadjuvant and adjuvant treatment with an immune	checkpoint inhibitor
	and		The individual has received	treatment with an immune checkpoint inhibitor for uni	respectable or metastatic malanama
		and	The individual has received	treatment with an infinure checkpoint inhibitor for this	resectable of metastatic metafiolita
			The individual meets renew	al criteria for pembrolizumab for unresectable or meta	astatic melanoma
Note):				
a) S	Stage I	IIB, IIIC, II	ID or IV melanoma defined a	s per American Joint Committee on Cancer (AJCC) 8	th Edition
				te surgical resection means either 13 weeks after rese	ection (primary or lymphadenectomy) or 13 weeks
p	prior to the scheduled date of the resection (primary or lymphadenectomy)				

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Name:		Surname:	Surname:
Address:		DOB:	Address:
		Address:	
Fax Number:	I mab - continued		Fax Number:
Initial application — stage III or IV resected melanoma - adjuvant Applications only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months. Prerequisites(tick boxes where appropriate)			
or	The individual is currently on treatr	nent with pembrolizumab and met all remaining criter	ria prior to commencing treatment
The individual has resected stage IIIB, IIIC, IIID or IV melanoma (excluding uveal) (see note a)		(see note a)	
Adjuvant treatment with pembrolizumab is rec		brolizumab is required	
	· —	ed prior funded systemic treatment in the adjuvant se	etting for stage IIIB, IIIC, IIID or IV melanoma
	Treatment must be in addition	n to complete surgical resection	
	Treatment must be initiated within 13 weeks of complete surgical resection, unless delay is necessary due to post-surgery recovery (see note b)		ss delay is necessary due to post-surgery
and Pembrolizumab must be administered as monotherapy			
	The individual has ECOG performance score 0-2		
		stered at a fixed dose of 200 mg every 3 weeks (or e	quivalent)
Note:			
a) Stage IIIB,	, IIIC, IIID or IV melanoma defined as	per American Joint Committee on Cancer (AJCC) 88	th Edition
b) Initiating tr	reatment within 13 weeks of complete	surgical resection means 13 weeks after resection (primary or lymphadenectomy)

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Name:			Surname:	Surname:
Address: .			DOB:	Address:
			Address:	
Fax Number	er:			Fax Number:
Pembrol	lizumab	- continued		
Renewal	— stage III	or IV resected melanoma -	adjuvant	
Prerequisites(tick boxes where appropriate) No evidence of disease rectained and Pembrolizumab must be ad		m a relevant specialist or any	relevant practitioner on the recommendation of a rele	vant specialist. Approvals valid for 4 months.
	and and	treatment course, including a	istered at a fixed dose of 200 mg every three weeks (any systemic neoadjuvant treatment d at signs of disease recurrence or at completion of 1 ng every 3 weeks), including any systemic neoadjuva	2 months total treatment course (equivalent to
The individual has received adjuvant treatment with an immune checkpoint inhibitor and The individual has metastatic or unresectable melanoma (excluding uveal) stage III or IV and The individual meets initial application criteria for pembrolizumab for unresectable or metastatic melanoma		III or IV		
or	and		adjuvant treatment with an immune checkpoint inhibit	
and The individual meets renewal criteria for pembrolizumab for unresectable or m			static melanoma	

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Reg No:	First Names:	First Names:
Name:	Surname:	Surname:
Address:	DOB:	Address:
	Address:	
Fax Number:Pembrolizumab - continued		Fax Number:
Initial application — unresectable or metastatic melanoma Applications only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist or any relevant practitioner on the recommendation of a relevant practitioner on the recommendation of a relevant process. The individual has metastatic or unresectable melanoma (excluding uveal) stage III or and Baseline measurement of overall tumour burden is documented clinically and radiologicand The individual has ECOG performance score of 0-2 The individual has not received funded nivolumab The individual has received an initial Special Authority approval for nivolum 12 weeks of starting treatment due to intolerance and The cancer did not progress while the individual was on nivolumab and The individual has been diagnosed in the metastatic or unresectable stage III or or The individual did not receive treatment in the perioperative setting with a PD-1/for or		vally ab and has discontinued nivolumab within
and	experience disease recurrence while on treatment wi experience disease recurrence within six months of c	

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Name:	Surname:	Surname:
Address:	DOB:	Address:
	Address:	
Fax Number:		Fax Number:
Pembrolizumab - continued		
Renewal — unresectable or metastatic melanor	ma, less than 24 months on treatment	
Prerequisites(tick boxes where appropriate) The individual's disease or The individual has state and T	relevant practitioner on the recommendation of a relevant practitioner on the recommendation of a relevant practitioner on the recommendation of a relevant see has had a complete response to treatment see has had a partial response to treatment	
and progression The individual has signs of d and	discontinued treatment with pembrolizumab for reassisease progression during previous treatment with pembrolizumab	sons other than severe toxicity or disease

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Address:	DOB:	Address:
	Address:	
Fax Number:		Fax Number:
Pembrolizumab - continued		
Renewal — unresectable or metastatic melano	ma, more than 24 months on treatment	
The individual has been on treatment and The individual has been on treatment and The individual's or The individual has or The individual has and Response to treatment the most recent treatment and the most recent treatment and The individual has predisease progression and The individual has signand	relevant practitioner on the recommendation of a relevant practitioner on the recommendation of a relevant for more than 24 months disease has had a complete response to treatment disease has had a partial response to treatment as stable disease t in target lesions has been determined by comparable	le radiologic or clinical assessment following or reasons other than severe toxicity or

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Name:	Surname:	Surname:
Address:	DOB:	Address:
	Address:	
Fax Number:		Fax Number:
Pembrolizumab - continued		
Prerequisites (tick boxes where appropriate) Patient has locally advanced or met and Patient has not had chemotherapy to and Patient has not received prior funder and For patients with non-squamous his EGFR or ALK tyrosine kinase unless and Pembrolizumab to be used as mondand	otherapy rming the disease expresses PD-L1 at a level greate	NSCLC sease does not express activating mutations of
There is documentation a validated test unless	n confirming the disease expresses PD-L1 at a level not possible to ascertain mined to be not in the best interest of the patient bas	
and	ximum dose of 200 mg every three weeks (or equiva	,

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Name):	Surname:	Surname:	
Addre	ess:	DOB:	Address:	
		Address:		
Fax N	lumber:		Fax Number:	
Peml	brolizumab - continued			
Rene	ewal — non-small cell lung cancer fi	rst line monotherapy		
Appli	ent approval Number (if known):ications only from a medical oncologist	or any relevant practitioner on the recor	nmendation of a medical oncologist. Approvals valid for 4 months.	
	or Patient's disease has	had a complete response to treatment		
	Patient has stable dis	eease		
	Response to treatment in taperiod	arget lesions has been determined by co	mparable radiologic assessment following the most recent treatment	
No evidence of disease progression		gression		
	The treatment remains clini	cally appropriate and patient is benefitting	opropriate and patient is benefitting from treatment	
	Pembrolizumab to be used	at a maximum dose of 200 mg every thr	aximum dose of 200 mg every three weeks (or equivalent)	
	Treatment with pembrolizur 3 weeks)	nab to cease after a total duration of 24	months from commencement (or equivalent of 35 cycles dosed every	
Initial application — non-small cell lung cancer first-line combination therapy Applications only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months. Prerequisites(tick boxes where appropriate)				
	Patient has locally advance	d or metastatic, unresectable, non-smal	cell lung cancer	
	The patient has not had che	emotherapy for their disease in the pallia	tive setting	
		or funded treatment with an immune che	eckpoint inhibitor for NSCLC	
	For patients with non-squar	nous histology there is documentation c se unless not possible to ascertain	onfirming that the disease does not express activating mutations of	
		in combination with platinum-based che	motherapy	
	Patient has an ECOG 0-2			
		at a maximum dose of 200 mg every thr	ee weeks (or equivalent) for a maximum of 16 weeks	
		verall tumour burden is documented clir	ically and radiologically	

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Name:	Surname:	Surname:
Address:	DOB:	Address:
	Address:	
Fax Number:		Fax Number:
Pembrolizumab - continued		
Renewal — non-small cell lung cancer first line	combination therapy	
Prerequisites(tick boxes where appropriate) Patient's disease has had a or	relevant practitioner on the recommendation of a me	dical oncologist. Approvals valid for 4 months.
Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent t period and		
No evidence of disease progressio	n	
The treatment remains clinically ap	propriate and patient is benefitting from treatment	
Pembrolizumab to be used at a ma	ximum dose of 200 mg every three weeks (or equiva	alent)
Treatment with pembrolizumab to o	cease after a total duration of 24 months from comme	encement (or equivalent of 35 cycles dosed every

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Address:	DOB:	Address:
	Address:	
Fax Number:		Fax Number:
Pembrolizumab - continued		
Prerequisites(tick boxes where appropriate)	relevant practitioner on the recommendation of a rele	
or	in pembrolizumab and met all remaining chiena pho	to commencing fleatment
or express ER, PR or HE	or de novo unresectable, inoperable locally advanced R2 IHC3+ or ISH+ [including FISH or other technolo or de novo metastatic triple-negative breast cancer (the	gy])
or ISH+ [including FISI	H or other technology])	
Patient is treated with palliati	ve intent	
Patient's cancer has confirme	and Patient's cancer has confirmed PD-L1 Combined Positive Score (CPS) is greater than or equal to 10	
	and Patient has received no prior systemic therapy in the palliative setting	
and Patient has an ECOG score	and Patient has an ECOG score of 0–2	
and Pembrolizumab is to be used in combination with chemotherapy		
and Baseline measurement of ov	erall tumour burden is documented clinically and rad	iologically
and	at a maximum dose of 200 mg every three weeks (

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Name:	Surname:	Surname:
Address:	DOB:	Address:
	Address:	
Fax Number:		Fax Number:
Pembrolizumab - continued		
Renewal — breast cancer, advanced		
Current approval Number (if known): Applications from any relevant practitioner. Approv Prerequisites(tick boxes where appropriate)		
or	complete response to treatment partial response to treatment	
and Pembrolizumab is to be used at a r	n sions has been determined by a comparable radiolog maximum dose of 200 mg every three weeks (or equion cease after a total duration of 24 months from com	ivalent)
Prerequisites(tick boxes where appropriate)	cell carcinoma relevant practitioner on the recommendation of a rele th pembrolizumab and met all remaining criteria prior	
carcinoma) that is incurable and Patient has not received prio	or systemic therapy in the recurrent or metastatic settic combined positive score (CPS) of greater than or equal to the combined positive score (CPS) of greater than or equal to the combined positive score (CPS) of greater than or equal to the combined positive score (CPS) of greater than or equal to the combined positive score (CPS) of greater than or equal to the combined positive score (CPS) of greater than or equal to the combined positive score (CPS) of greater than or equal to the combined positive score (CPS) of greater than or equal to the combined positive score (CPS) of greater than or equal to the combined positive score (CPS) of greater than or equal to the combined positive score (CPS) of greater than or equal to the combined positive score (CPS) of greater than or equal to the combined positive score (CPS) of greater than or equal to the combined positive score (CPS) of greater than or equal to the combined positive score (CPS) or greater than or equal to the combined positive score (CPS) or greater than or equal to the combined positive score (CPS) or greater than or equal to the combined positive score (CPS) or greater than or equal to the combined positive score (CPS) or greater than or equal to the combined positive score (CPS) or greater than or equal to the combined positive score (CPS) or greater than or equal to the combined positive score (CPS) or greater than or equal to the combined positive score (CPS) or greater than or equal to the combined positive score (CPS) or greater than or equal to the combined positive score (CPS) or greater than or equal to the combined positive score (CPS) or greater than or equal to the combined positive score (CPS) or greater than or equal to the combined positive score (CPS) or greater than or equal to the combined positive score (CPS) or greater than or equal to the combined positive score (CPS) or greater than or equal to the combined positive score (CPS) or greater than or equal to the combined positive score (CPS) or greater than or equal to the comb	ng
and Pembrolizumab to be to	used in combination with platinum-based chemothera	ару
and Pembrolizumab is to be used	d at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks

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Name:			Surname:	Surname:
Address:			DOB:	Address:
			Address:	
Fax Number:				Fax Number:
Pembrolizur Renewal — he		continued d neck squamous cell carc	inoma	
Current approv	al Num	nber (if known):		
Applications fro	om any	relevant practitioner. Approximates where appropriate)		
or		Patient's disease has had a	complete response to treatment	
	Patient's disease has had a partial response to treatment			
	Patient has stable disease			
and No evidence of disease progression and				
and	Pemb	prolizumab is to be used at a	maximum dose of 200 mg every three weeks (or equi	ivalent)
		ment with pembrolizumab is t 3 weeks)	o cease after a total duration of 24 months from com	mencement (or equivalent of 35 cycles dosed
Applications of	nly fror	MSI-H/dMMR advanced co m a relevant specialist or any exes where appropriate)	lorectal cancer relevant practitioner on the recommendation of a rele	evant specialist. Approvals valid for 4 months.
or			with pembrolizumab and met all remaining criteria pr	rior to commencing treatment
	or	Individual has deficier	nt mismatch repair (dMMR) or microsatellite instability	-high (MSI-H) metastatic colorectal cancer
		Individual has deficier	nt mismatch repair (dMMR) or microsatellite instability	-high (MSI-H) unresectable colorectal cancer
an		Individual is treated with pall	iative intent	
an		Individual has not previously	received funded treatment with pembrolizumab for N	//ISI-H/dMMR advanced colorectal cancer
an		Individual has an ECOG per	formance score of 0-2	
		Baseline measurement of ov	verall tumour burden is documented clinically and rad	iologically
an		Pembrolizumab to be used a	at a maximum dose of 200 mg every three weeks (or	equivalent) for a maximum of 16 weeks

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Name:	Surname:	Surname:		
Address:	DOB:	Address:		
	Address:			
Fax Number:		Fax Number:		
Pembrolizumab - continued				
Renewal — MSI-H/dMMR advanced colorectal o	eancer			
Current approval Number (if known):				
Applications from any relevant practitioner. Approv Prerequisites (tick boxes where appropriate)	als valid for 4 months.			
No evidence of disease progression	n			
	aximum dose of 200 mg every three weeks (or equiva	alent)		
Treatment with pembrolizumab is to every 3 weeks)	o cease after a total duration of 24 months from com	mencement (or equivalent of 35 cycles dosed		
Initial application — Urothelial carcinoma Applications only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months. Prerequisites(tick boxes where appropriate)				
Patient is currently on treatment wi	th pembrolizumab and met all remaining criteria prior	to commencing treatment		
Patient has inoperable locall	y advanced (T4) or metastatic urothelial carcinoma			
Patient has an ECOG perfor	mance score of 0-2			
Patient has documented dise	ease progression following treatment with chemother	ару		
Pembrolizumab to be used a 16 weeks	s monotherapy at a maximum dose of 200 mg every	three weeks (or equivalent) for a maximum of		
Renewal — Urothelial carcinoma				
nenewai — Oromenai caremonia				
Current approval Number (if known): Applications only from a relevant specialist or any in Prerequisites (tick boxes where appropriate)	relevant practitioner on the recommendation of a rele	vant specialist. Approvals valid for 4 months.		
or Patient's disease has had a	complete response to treatment			
Patient's disease has had a or	partial response to treatment			
Patient has stable disease				
and No evidence of disease progressio	n			
and Pembrolizumab to be used at a ma	aximum dose of 200 mg every three weeks (or equiva	alent)		
and Treatment with pembrolizumab is to every 3 weeks)	o cease after a total duration of 24 months from com	mencement (or equivalent of 35 cycles dosed		

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Reg N	lo:				First Names:	First Names:
Name	:				Surname:	Surname:
Addre	ss:				DOB:	Address:
					Address:	
Fax N	umber	·				Fax Number:
Peml	broliz	zuma	ab - d	continued		
Appl	ication	ns only tes(tic	or	es where appropriate) ual is currently on treatment and Individual has re Individual is ine Individual has relapse	relevant practitioner on the recommendation of a relevant practitioner on the recommendation of a relevant practitioner on the recommendation of a relevant product of the	ore lines of chemotherapy Indergone an autologous stem cell transplant Dory Hodgkin lymphoma
Renewal — relapsed/refractory Hodgkin lymphoma						
Current approval Number (if known):						
Applications only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months. Prerequisites(tick boxes where appropriate)						
	Patient has received a partial or complete response to pembrolizumab					
	and [ent with pembrolizumab is t 3 weeks)	o cease after a total duration of 24 months from com	mencement (or equivalent of 35 cycles dosed