SA2553 - 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				
Initial application — stage III or IV resectable m Applications only from a relevant specialist or any Prerequisites(tick boxes where appropriate)	elanoma - neoadjuvant relevant practitioner on the recommendation of a rele	evant specialist. Approvals valid for 4 months.		
The individual has resectable stage	e IIIB, IIIC, IIID or IV melanoma (excluding uveal) (se	e note)		
The individual has not received price	ne individual has not received prior funded systemic treatment in the perioperative setting for their stage IIIB, IIIC, IIID or IV melanoma			
Treatment must be prior to complete surgical resection				
Pembrolizumab must be administe				
	The individual has ECOG performance score 0-2			
and Pembrolizumab to be administered	Pembrolizumab to be administered at a fixed dose of 200 mg every 3 weeks (or equivalent)			

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Name:			Surname:	Surname:	
Addre	ess:			DOB:	Address:
				Address:	
					Fax Number:
Pem	broli	zumab	- continued		
Curr	ent ap	proval Nur	nber (if known):n a relevant specialist or any oxes where appropriate)	-	vant specialist. Approvals valid for 4 months.
and The individual meets initial a		The individual meets initial a	neoadjuvant treatment with an immune checkpoint in application criteria for pembrolizumab for stage III or I' neoadjuvant and adjuvant treatment with an immune	V resected melanoma – adjuvant	
	and The individual meets renewa			val criteria for pembrolizumab for stage III or IV resected melanoma – adjuvant	
and The individual has metastati		The individual has metastati	d neoadjuvant and adjuvant treatment with an immune checkpoint inhibitor tic or unresectable melanoma (excluding uveal) stage III or IV application criteria for pembrolizumab for unresectable or metastatic melanoma		
	or	and and	The individual has received	neoadjuvant and adjuvant treatment with an immune treatment with an immune checkpoint inhibitor for unreal criteria for pembrolizumab for unresectable or meta	resectable or metastatic melanoma
Note	: :				
a) S	a) Stage IIIB, IIIC, IIID or IV melanoma defined as per American Joint Committee on Cancer (AJCC) 8th Edition				
	b) Initiating treatment within 13 weeks of complete surgical resection means either 13 weeks after resection (primary or lymphadenectomy) or 13 weeks prior to the scheduled date of the resection (primary or lymphadenectomy)				

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Name:	Surname:	Surname:
Address:	DOB:	Address:
	Address:	
Fax Number:		Fax Number:
Pembrolizumab - continued		
Prerequisites(tick boxes where appropriate) The individual has resected stage I and Adjuvant treatment with pembrolizu and The individual has not received price and Treatment must be in addition to color and Treatment must be initiated within the note b) and Pembrolizumab must be administer and The individual has ECOG performal and	IIIB, IIIC, IIID or IV melanoma (excluding uveal) (see amab is required or funded systemic treatment in the adjuvant setting fromplete surgical resection 13 weeks of complete surgical resection, unless delayed as monotherapy ance score 0-2	note a) or stage IIIB, IIIC, IIID or IV melanoma y is necessary due to post-surgery recovery (see
Pembrolizumab to be administered at a fixed dose of 200 mg every 3 weeks (or equivalent)		ent)
Note: a) Stage IIIB, IIIC, IIID or IV melanoma defined as per American Joint Committee on Cancer (AJCC) 8th Edition b) Initiating treatment within 13 weeks of complete surgical resection means 13 weeks after resection (primary or lymphadenectomy)		

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Address:		DOB:	Address:
		Address:	
Fax Numb	er:		Fax Number:
Pembro	lizumab - continued		
Renewal	— stage III or IV resected melanoma -	adjuvant	
Application	No evidence of disease recu and Pembrolizumab must be admini	relevant practitioner on the recommendation of a rele	
		d at signs of disease recurrence or at completion of 1 ng every 3 weeks), including any systemic neoadjuva	
or	and The individual has metastation	adjuvant treatment with an immune checkpoint inhibitor or unresectable melanoma (excluding uveal) stage pplication criteria for pembrolizumab for unresectable	III or IV
or			
	The individual has received a	adjuvant treatment with an immune checkpoint inhibi	tor
	The individual has received and	treatment with an immune checkpoint inhibitor for un	resectable or metastatic melanoma
		criteria for pembrolizumab for unresectable or metastatic melanoma	

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Reg No:	. First Names:	First Names:
Name:	. Surname:	Surname:
Address:	. DOB:	Address:
Fax Number:		Fax Number:
Pembrolizumab - continued		
and Baseline measurement of overal and The individual has ECOG perfor and The individual has not rec or The individual has r 12 weeks of starting		cally
or The individual did not received and The individual received and The individual did not received and The individual did not received and	riagnosed in the metastatic or unresectable stage III or sive treatment in the perioperative setting with a PD-1/F wed treatment in the perioperative setting with a PD-1/F of experience disease recurrence while on treatment we of experience disease recurrence within six months of a r	PD-L1 inhibitor PD-L1 inhibitor ith that PD-1/PD-L1 inhibitor

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Name:	Surname:	Surname:
Address:	DOB:	Address:
	Address:	
Fax Number:		Fax Number:
Pembrolizumab - continued		
Renewal — unresectable or metastatic melanon	na, less than 24 months on treatment	
Prerequisites(tick boxes where appropriate) The individual's diseas or The individual has stable and Response to treatment in target reatment period The individual has previously progression and The individual has signs of diand	elevant practitioner on the recommendation of a relevant practitioner on the recommendation of a relevant process of the second	ologic assessment following the most recent

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Name:	Surname:	Surname:
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	Address:	
Fax Number:		Fax Number:
Pembrolizumab - continued		
The individual has been on treatment or The individual has been on treatment or The individual's or The individual's or The individual has been on treatment in the individual's or The individual has predisease progression and The individual has signed and The individual has signed and	ent for more than 24 months disease has had a complete response to treatment disease has had a partial response to treatment as stable disease	le radiologic or clinical assessment following or reasons other than severe toxicity or

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Reg No:	First Names:	First Names:
Name:	Surname:	Surname:
Address:	DOB:	Address:
	Address:	
Fax Number:		Fax Number:
Pembrolizumab - continued		
Initial application — non-small cell lung cance Applications only from a medical oncologist or ar Prerequisites(tick boxes where appropriate)	er first-line monotherapy by relevant practitioner on the recommendation of a m	edical oncologist. Approvals valid for 4 months.
and Patient has not had chemotherape and Patient has not received prior functions and For patients with non-squamous heart EGFR or ALK tyrosine kinase unland There is documentation convalidated test unless not poor There is documentation a validated test unless and	notherapy firming the disease expresses PD-L1 at a level great	er than or equal to 50% as determined by a greater than or equal to 1% as determined by
and Patient has an ECOG 0-2 and Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks and Baseline measurement of overall tumour burden is documented clinically and radiologically		·
Daseline measurement of overall	Imour burden is documented clinically and radiologically	

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APPLICANT (stamp or sticker acceptable)		tamp or sticker acceptable)	PATIENT NHI:	REFERRER Reg No:
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Name:			Surname:	Surname:
Addre	ss:		DOB:	Address:
			Address:	
Fax N	umber:			Fax Number:
Peml	brolizui	mab - continued		
Rene	wal — ne	on-small cell lung cancer first line	e monotherapy	
Curre	ant annro	al Number (if known):		
			relevant practitioner on the recommendation of a me	dical oncologist. Approvals valid for 4 months.
		(tick boxes where appropriate)	·	5 11
		Detient's disease has had a	complete veep each to treatment	
	or		complete response to treatment	
	or		partial response to treatment	
		Patient has stable disease		
	and	Response to treatment in target le	sions has been determined by comparable radiologic	assessment following the most recent treatment
	and	period	sions has been determined by comparable radiologic	assessment following the most recent treatment
		No evidence of disease progression	on	
	and	The treatment remains clinically ap	opropriate and patient is benefitting from treatment	
	and	Pembrolizumab to be used at a ma	aximum dose of 200 mg every three weeks (or equiva	alent)
	and		cease after a total duration of 24 months from comme	·
		3 weeks)		pricement (er equivalent er ee eyelee deeed eter)
Initio	Lonnline	tion — non-small cell lung cance	first line combination thereny	
Appl	ications o	nly from a medical oncologist or any	y relevant practitioner on the recommendation of a me	edical oncologist. Approvals valid for 4 months.
Prere	equisites	(tick boxes where appropriate)		
	and	Patient has locally advanced or me	etastatic, unresectable, non-small cell lung cancer	
		The patient has not had chemothe	rapy for their disease in the palliative setting	
	and	Patient has not received prior fund	ed treatment with an immune checkpoint inhibitor for	NSCLC
	and	For natients with non-squamous h	istology there is documentation confirming that the di	sease does not express activating mutations of
	and	EGFR or ALK tyrosine kinase unle		decade does not express activating mutations of
			nbination with platinum-based chemotherapy	
	and	Patient has an ECOG 0-2		
	and	Pembrolizumab to be used at a ma	aximum dose of 200 mg every three weeks (or equiva	alent) for a maximum of 16 weeks
	and		umour burden is documented clinically and radiologic	,
	ш	Dassine measurement or overall t	amour surden is documented diffically and radiologic	, any

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APPLICANT (stamp or sticker acceptable)			PATIENT NHI:	REFERRER Reg No:
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Name:			Surname:	Surname:
Addres	ss:		DOB:	Address:
			Address:	
Fax Nu	ımber:			Fax Number:
Pemb	rolizu	ımab - continued		
Rene	wal — r	non-small cell lung cancer first line	combination therapy	
Curre	nt appro	oval Number (if known):		
		only from a medical oncologist or any s(tick boxes where appropriate)	relevant practitioner on the recommendation of a me	edical oncologist. Approvals valid for 4 months.
	0		complete response to treatment	
	0		partial response to treatment	
		Patient has stable disease		
and Response to treatment in target les period and No evidence of disease progressio and			sions has been determined by comparable radiologic	assessment following the most recent treatment
			on	
The treatment remains clinically ap and Pembrolizumab to be used at a ma		The treatment remains clinically ap	propriate and patient is benefitting from treatment	
		Pembrolizumab to be used at a ma	eximum dose of 200 mg every three weeks (or equiva	alent)
Treatment with pembrolizumab to o			ease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every	

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Reg No:				First Names:	First Names:
Name:				Surname:	Surname:
Address:				DOB:	Address:
				Address:	
Fax Numbe	ər:				Fax Number:
Pembrol	izuma	b -	continued		
Application	ons only sites(ticl	fron k bo	xes where appropriate)	relevant practitioner on the recommendation of a rele	
or express ER, PR or HE		express ER, PR or HE	or de novo unresectable, inoperable locally advanced R2 IHC3+ or ISH+ [including FISH or other technology or de novo metastatic triple-negative breast cancer (the H or other technology])	gy])	
	and		Patient is treated with palliati	ve intent	
	and		Patient's cancer has confirme	ed 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	of 0-2	
	and		Pembrolizumab is to be used	I in combination with chemotherapy	
	and		Baseline measurement of ov	erall tumour burden is documented clinically and rad	iologically
			Pembrolizumab is to be used	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 — 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 Response to treatment in target lesions has been determined by a comparable radiologic assessment following the most recent treatment period and Pembrolizumab is to be used at a maximum dose of 200 mg every three weeks (or equivalent) and Treatment with pembrolizumab is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks)					
Initial application — head and neck squamous Applications only from a relevant specialist or any Prerequisites(tick boxes where appropriate)	cell carcinoma relevant practitioner on the recommendation of a rele	evant specialist. Approvals valid for 4 months.			
Patient is currently on treatment wi	th pembrolizumab and met all remaining criteria prior	to commencing treatment			
carcinoma) that is incurable	astatic head and neck squamous cell carcinoma of m by local therapies or systemic therapy in the recurrent or metastatic setti				
	combined positive score (CPS) of greater than or eq	ual to 1			
Patient has an ECOG perfor	mance score of 0-2				
Pembrolizumab to be	used in combination with platinum-based chemothera	ару			
Pembrolizumab to be	used as monotherapy				
and Pembrolizumab is to be used	d at a maximum dose of 200 mg every three weeks (o	or equivalent) for a maximum of 16 weeks			

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APPLICANT (stamp or sticker acceptable)		or sticker acceptable)	PATIENT NHI:	REFERRER Reg No:	
Reg No:			First Names:	First Names:	
Name:				Surname:	Surname:
Addres	s:			DOB:	Address:
				Address:	
Fax Nu	ımber	:			Fax Number:
			- continued		
Rene	wal –	- head ar	nd neck squamous cell c	arcinoma	
Curre	nt app	oroval Nu	mber (if known):		
			y relevant practitioner. Appoxes where appropriate)	provals valid for 4 months.	
	[
		or _	Patient's disease has ha	d a complete response to treatment	
	Patient's disease has had a partial response to treatment or				
	Patient has stable disease				
	and				
	and	No e	vidence of disease progre	ssion	
	and	Pem	brolizumab is to be used a	t a maximum dose of 200 mg every three weeks (or equ	uivalent)
			tment with pembrolizumab y 3 weeks)	is to cease after a total duration of 24 months from con	nmencement (or equivalent of 35 cycles dosed
L			,		
			– MSI-H/dMMR advanced	colorectal cancer any relevant practitioner on the recommendation of a re	levant specialist Approvals valid for 4 months
		-	oxes where appropriate)	any relevant precinition on the recommendation of the	iovain opeoiane. Approvaie valid for Thioritie.
		Indiv	ridual is currently on treatm	ent with pembrolizumab and met all remaining criteria p	prior to commencing treatment
	or				
		OI		cient mismatch repair (dMMR) or microsatellite instabilit	y-high (MSI-H) metastatic colorectal cancer
				cient mismatch repair (dMMR) or microsatellite instabilit	y-high (MSI-H) unresectable colorectal cancer
		and	Individual in treated with	nalliativa intent	
		and	Individual is treated with		
		and	Individual has not previous	usly received funded treatment with pembrolizumab for	MSI-H/dMMR advanced colorectal cancer
		and	Individual has an ECOG	performance score of 0-2	
			Baseline measurement of	f overall tumour burden is documented clinically and rac	diologically
		and	Pembrolizumab to be use	ed at a maximum dose of 200 mg every three weeks (or	equivalent) for a maximum of 16 weeks
L	L				

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Name: Surname: Surname: Address: DOB: Address: Address: Address: Fax Number:						
Address:	First Names:					
Address: Fax Number: Fax Number: Pembrolizumab - continued Renewal — MSI-H/dMMR advanced colorectal cancer Current approval Number (if known):						
Fax Number: Fax Nu						
Pembrolizumab - continued Renewal — MSI-H/dMMR advanced colorectal cancer Current approval Number (if known):						
Pembrolizumab - continued Renewal — MSI-H/dMMR advanced colorectal cancer Current approval Number (if known):						
Renewal — MSI-H/dMMR advanced colorectal cancer Current approval Number (if known):						
Current approval Number (if known):						
Applications from any relevant practitioner. Approvals valid for 4 months. Prerequisites(tick boxes where appropriate) No evidence of disease progression and Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent)						
Treatment with pembrolizumab is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dose every 3 weeks)	d					
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 with pembrolizumab and met all remaining criteria prior to commencing treatment or						
Patient has inoperable locally advanced (T4) or metastatic urothelial carcinoma						
Patient has an ECOG performance score of 0-2 and						
Patient has documented disease progression following treatment with chemotherapy and						
Pembrolizumab to be used as monotherapy at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum 16 weeks	of					
Renewal — Urothelial carcinoma						
Current approval Number (if known):						
Patient's disease has had a complete response to treatment or	$\neg \neg$					
Patient's disease has had a partial response to treatment						
Patient has stable disease						
and No evidence of disease progression						
Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent)						
and Treatment with pembrolizumab is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dose every 3 weeks)						

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Reg N	lo:				First Names:	First Names:
Name	:				Surname:	Surname:
Addre	ss:				DOB:	Address:
					Address:	
Fax N	umbe	er:				Fax Number:
Pem	broli	izum	ab -	continued		
		ites(tio	or I	ual is currently on treatment Individual has re and Individual is ine Individual has relapse	with pembrolizumab and met all remaining criteria prelapsed/refractory Hodgkin lymphoma after two or modigible for autologous stem cell transplant d/refractory Hodgkin lymphoma and has previously use received funded pembrolizumab for relapsed/refractistered at doses no greater than 200 mg once every contents.	ore lines of chemotherapy Indergone an autologous stem cell transplant ory Hodgkin lymphoma
Rene	ewal -	— rela	psed/	refractory Hodgkin lymph	oma	
Appli	cation	ns only	from	per (if known):a relevant specialist or any es where appropriate)	relevant practitioner on the recommendation of a rele	vant specialist. Approvals valid for 6 months.
	_	F	Patient	t has received a partial or co	emplete 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