SA2386 - Pembrolizumab

MSI-H/dMMR advanced colorectal cancer - Initial application MSI-H/dMMR advanced colorectal cancer - Renewal Urothelial carcinoma - Initial application Urothelial carcinoma - Renewal Breast cancer, advanced - Initial application Breast cancer, advanced - Renewal Head and neck squamous cell carcinoma - Initial application Head and neck squamous cell carcinoma - Renewal Non-small cell lung cancer first line combination therapy - Renewal Non-small cell lung cancer first-line combination therapy - Initial application Non-small cell lung cancer first-line monotherapy - Initial application Non-small cell lung cancer first-line monotherapy - Initial application Relapsed/refractory Hodgkin lymphoma - Initial application Relapsed/refractory Hodgkin lymphoma - Renewal	10 10 10 8 8 9 6 5 5
Relapsed/refractory Hodgkin lymphoma - Initial application	11 11 2

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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 Num	ber	:						Fax Number:
Pembro	oliz	zum	nab					
Applicat	tion	s on	ly fro		-		recommendation of a medic	al oncologist. Approvals valid for 4 months.
ar	l nd		Patie	nt has meta	static or unresect	able melanoma (excludir	ng uveal) stage III or IV	
ar	_ nd		Base	line measur	ement of overall t	umour burden is docume	ented clinically and radiologi	cally
ar			The	oatient has E	ECOG performan	ce score of 0-2		
ai	[٥.		Patient has	not received fun	ded nivolumab		
		or	ar	of sta	arting treatment c	an initial Special Authorit due to intolerance ogress while the patient		d has discontinued nivolumab within 12 weeks
ar	nd [onfirming that the disease progress		ed and acknowledges that f	unded treatment with pembrolizumab will not be
Renewa	ıl —	- un	resec	table or me	etastatic melano	ma, less than 24 month	ns on treatment	
Current	app	orova	al Nur	nber (if knov	vn):			
Applicati	ions	s onl	y fror	`	oncologist or med			al oncologist. Approvals valid for 4 months.
				Patie	ent's disease has	had a complete respons	e to treatment	
			or			had a partial response to		
			or		ent has stable dis	ease		
		and	 	Response treatment p		rget lesions has been de	termined by comparable rad	liologic assessment following the most recent
or		and		The treatm	ent remains clinic	cally appropriate and the	patient is benefitting from th	ne treatment
		and		Patient has	previously disco	ntinued treatment with p	embrolizumab for reasons o	ther than severe toxicity or disease progression
				Patient has	signs of disease	progression		
	and		Disease ha	as not progressed	I during previous treatme	nt with pembrolizumab		

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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 - continu	ued		
Patient has been on treatment for and Patient's diseas or Patient's diseas or Patient has state and Response to treatment the most recent treatment the most recent treatment and The treatment remains or Patient has previously progression and Patient has signs of diand		ical practitioner on the recommendation of a medical more than 24 months has had a complete response to treatment has had a partial response to treatment le disease in target lesions has been determined by comparable ent period clinically appropriate and the patient is benefitting from	e radiologic or clinical assessment following om the treatment ons other than severe toxicity or disease

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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: Pembrolizumab - continued		Fax Number:
Prerequisites(tick boxes where appropriate) Patient has locally advanced or metand Patient has not had chemotherapy and Patient has not received prior funderand	tastatic, unresectable, non-small cell lung cancer for their disease in the palliative setting ed treatment with an immune checkpoint inhibitor for stology there is documentation confirming that the dises not possible to ascertain	NSCLC
or validated test unless not poss There is documentation a validated test unless and	rming the disease expresses PD-L1 at a level greate sible to ascertain 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 base	greater than or equal to 1% as determined by
and	ximum dose of 200 mg every three weeks (or equiva	,

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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 - continued				
Renewal — non-small cell lung cancer first line	e monotherapy			
Current approval Number (if known):				
, ,	relevant practitioner on the recommendation of a m	edical oncologist. Approvals valid for 4 months.		
Prerequisites(tick boxes where appropriate)				
Patient's disease has had a	complete response to treatment			
or				
or	partial response to treatment			
Patient has stable disease				
Response to treatment in target le	sions has been determined by comparable radiologi	c assessment following the most recent treatment		
period and				
No evidence of disease progression	on			
The treatment remains clinically a	appropriate and patient is benefitting from treatment			
Pembrolizumab to be used at a ma	naximum dose of 200 mg every three weeks (or equivalent)			
	cease after a total duration of 24 months from comm	nencement (or equivalent of 35 cycles dosed every		
3 weeks)				
Initial application — non-small cell lung cancel Applications only from a medical oncologist or any Prerequisites(tick boxes where appropriate)	r first-line combination therapy y relevant practitioner on the recommendation of a m	nedical oncologist. Approvals valid for 4 months.		
	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 prior funded treatment with an immune checkpoint inhibitor for NSCLC			
and For natients with non-squamous h	istology there is documentation confirming that the c	lisease does not express activating mutations of		
EGFR or ALK tyrosine kinase unle		isocase does not express activating matations of		
Pembrolizumab to be used in com	bination with platinum-based chemotherapy			
Patient has an ECOG 0-2				
and Pembrolizumab to be used at a magnetic process.	maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks			
and Baseline measurement of overall t	umour burden is documented clinically and radiologi	ically		

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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 - continued			
Renewal — non-small cell lung cancer first line	combination therapy		
Current approval Number (if known):			
Applications only from a medical oncologist or any Prerequisites (tick boxes where appropriate)	relevant practitioner on the recommendation of a me	dical oncologist. Approvals valid for 4 months.	
Patient's disease has had a	complete response to treatment		
or			
Patient's disease has had a	partial response to treatment		
Patient has stable disease			
period	sions has been determined by comparable radiologic	assessment following the most recent treatment	
No evidence of disease progressio	n		
	propriate and patient is benefitting from treatment		
	uximum dose of 200 mg every three weeks (or equiva	alent)	
Treatment with pembrolizumab to c 3 weeks)	cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every		

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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:
Address:			DOB:	Address:
			Address:	
Fax Number	:			Fax Number:
Pembroliz	rumah	- continued		
	Patient has recurrent of express ER, PR or HE Patient has recurrent of Patient has recurrent has r		th pembrolizumab and met all remaining criteria prio	r to commencing treatment
			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 or other technology])	gy])
and		Patient is treated with palliat	ive intent 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	
	Patient has an ECOG score		of 0-2	
	and	Pembrolizumab is to be used	d in combination with chemotherapy	
	and Baseline measurement of ov		verall tumour burden is documented clinically and rad	liologically
	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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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 - continued					
Renewal — breast cancer, advanced					
Current approval Number (if known):					
or	complete response to treatment partial response to treatment				
No evidence of disease progression and Response to treatment in target less treatment period and Pembrolizumab is to be used at a rand	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				
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 ec	jual to 1			
and Patient has an ECOG perfor	mance score of 0-2				
and Pembrolizumab to be	used in combination with platinum-based chemothera	ару			
or Pembrolizumab to be	·				
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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	First Names:	First Names:			
	Surname:	Surname:			
	DOB:	Address:			
	Address:				
ber:		Fax Number:			
olizumab - continued					
I — head and neck squamous cell carc	inoma				
approval Number (if known):					
isites(tick boxes where appropriate)					
Patient's disease has had a	complete response to treatment				
Or Patient's disease has had a	nartial response to treatment				
or	partial response to treatment				
Patient has stable disease					
and No evidence of disease progression					
and Pembrolizumab is to be used at a maximum dose of 200 mg every three weeks (or equivalent)					
and					
every 3 weeks)		monocinom (or equivalent or ee eyelee deeed			
		evant specialist. Approvals valid for 4 months.			
Patient is currently on treatment w	ith pembrolizumab and met all remaining criteria prior	r to commencing treatment			
	nismatch repair (dMMR) or microsatellite instability-hi	gh (MSI-H) metastatic colorectal cancer			
	nismatch repair (dMMR) or microsatellite instability-hi	gh (MSI-H) unresectable colorectal cancer			
The second secon	ive intent				
Patient has not previously re	eceived funded treatment with pembrolizumab				
Patient has an ECOG perfor	rmance score of 0-2				
Baseline measurement of or	verall tumour burden is documented clinically and rad	iologically			
	at a maximum dose of 200 mg every three weeks (or	equivalent) for a maximum of 16 weeks			
	ber:	DOB: Address: Approval Number (if known): In head and neck squamous cell carcinoma Approval Number (if known): In head and neck squamous cell carcinoma Approval Number (if known): In head and neck squamous cell carcinoma Approval Number (if known): In Patient's disease has had a complete response to treatment In Patient's disease has had a partial response to treatment In Patient has stable disease Add No evidence of disease progression In Pembrolizumab is to be used at a maximum dose of 200 mg every three weeks (or equivalent of the complete response to treatment of the recommendation of 24 months from complete response to treatment with pembrolizumab is to cease after a total duration of 24 months from complete response to treatment with pembrolizumab is to cease after a total duration of 24 months from complete response to treatment with pembrolizumab and relevant specialist or any relevant practitioner on the recommendation of a relevant practical practical practi			

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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 - 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 Prerequisites(tick boxes where appropriate)	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
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 representation of the properties of the pro	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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Name:	Surname:	Surname:
Address:	DOB:	Address:
	Address:	
Fax Number:		Fax Number:
Pembrolizumab - continued		
Prerequisites (tick boxes where appropriate) Patient is currently on treatment or Patient has and Patient has relaps and Patient has not previous and Patient has not previous	any relevant practitioner on the recommendation of a relevant practitioner on the recommendation of a release of the second seco	e lines of chemotherapy dergone an autologous stem cell transplant
Renewal — relapsed/refractory Hodgkin lyr	nphoma	
Current approval Number (if known):		and an electric Annual control (and an electric control contro
Applications only from a relevant specialist or a Prerequisites (tick boxes where appropriate)	any relevant practitioner on the recommendation of a rele	evant specialist. Approvals valid for 6 months.
· · ·	or complete response to pembrolizumab	
Treatment with pembrolizumak every 3 weeks)	is to cease after a total duration of 24 months from con	nmencement (or equivalent of 35 cycles dosed