

Attachment A

Summary of PD-1 and PD-L1 registration and reimbursement dates

Drug: nivolumab [Opdivo, BMSA]

Bolded PBAC consideration dates = positive recommendation

Indication	FDA Approval	EMA approval (CHMP positive opinion)	TGA evaluation commenced	TGA approval	PBAC consideration			PBS listing
					First	Second	Third and subsequent	
Treatment of patients with unresectable or metastatic melanoma	22 December 2014	24 September 2015	[REDACTED]	11 January 2016	July 2015	November 2015	-	1 May 2016
Adjuvant treatment of patients with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection	20 December 2017	28 June 2018	23 October 2017	23 April 2018	July 2018	March 2019		
Treatment of locally advanced or metastatic squamous NSCLC with progression on or after prior chemotherapy	4 March 2015	24 September 2015	[REDACTED]	11 January 2016	March 2016	November 2016	March 2017¹	1 August 2017
Treatment of locally advanced or metastatic non-squamous NSCLC with progression on or after prior chemotherapy.	9 October 2015	25 February 2016	[REDACTED]	17 February 2016	March 2016	November 2016	March 2017¹	1 August 2017
Treatment of patients with advanced clear RCC after prior anti-angiogenic therapy	23 November 2015	25 February 2016	[REDACTED]	18 November 2016	July 2016	November 2016	March 2017²	1 August 2017
Treatment of patients with relapsed or refractory cHL after autologous stem cell transplant and treatment with brentuximab vedotin	17 May 2016	13 October 2016	31 May 2016	25 May 2017	November 2017 (withdrawn prior to consideration)			
Treatment of recurrent or metastatic squamous cell cancer of the head and neck in patients progressing on or after platinum-based therapy	10 November 2016	23 March 2017	2 September 2016	7 July 2017	November 2017	March 2018		1 August 2018
Treatment of patients with locally advanced unresectable or metastatic urothelial	2 February 2017	21 April 2017	31 January 2017	6 February 2018				

Indication	FDA Approval	EMA approval (CHMP positive opinion)	TGA evaluation commenced	TGA approval	PBAC consideration			PBS listing
					First	Second	Third and subsequent	
carcinoma after prior platinum-containing therapy								
In combination with ipilimumab for the treatment of patients with unresectable or metastatic melanoma ³	30 September 2015	1 April 2016	[REDACTED] / 1 August 2017	7 January 2016 / 4 July 2018	November 2015 ³	March 2017 ³	July 2018	1 December 2018
In combination with ipilimumab, for the treatment of patients with intermediate/poor-risk, previously untreated advanced RCC	16 April 2018	15 November 2018	28 February 2018	31 October 2018	July 2018	November 2018		
Treatment of patients with hepatocellular carcinoma after prior sorafenib therapy	22 September 2017	withdrawn	1 August 2017	17 September 2018				
[REDACTED]			[REDACTED]					
[REDACTED]			[REDACTED]					

1. Combined non-squamous and squamous consideration

2. Initial indication approved in January 2016 included requirement for M1c disease or elevated lactic dehydrogenase

Drug: pembrolizumab [Keytruda, MSD]

Bolded PBAC consideration dates = positive recommendation

Indication	FDA Approval	EMA approval (CHMP positive opinion)	TGA evaluation commenced	TGA approval	PBAC consideration			PBS listing
					First	Second	Third and subsequent	
Unresectable or metastatic melanoma in adults	18 December 2015	21 May 2015	██████	16 April 2015	March 2015			1 September 2015
First-line treatment of patients with metastatic NSCLC whose tumours express PD-L1 with a greater than or equal to 50% tumour proportion score (TPS) as determined by a validated test, with no EGFR or ALK genomic tumour aberrations	24 October 2016	15 December 2016	30 September 2016	3 March 2017	March 2017	November 2017	March 2018 July 2018	1 November 2018
In combination with pemetrexed and platinum chemotherapy, is indicated for the first-line treatment of patients with metastatic non-squamous NSCLC	10 May* 2017	26 July 2018	2 May 2017	8 June 2018	November 2018			
Treatment of patients with advanced NSCLC whose tumours express PD-L1 with a greater than or equal to 1% TPS as determined by a validated test and who have received platinum-containing chemotherapy.	24 October 2016	23 June 2016	30 September 2016	3 March 2017	November 2016			
Recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) with disease progression on or after platinum-containing chemotherapy	5 August 2016	26 July 2018	30 June 2016	20 March 2017	July 2018			
Relapsed or refractory classical Hodgkin's Lymphoma: 1. following autologous stem cell transplant (ASCT) or 2. following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option.	15 March 2017	23 March 2017	31 October 2016	1 September 2017	July 2017	August 2017		1 May 2018

Indication	FDA Approval	EMA approval (CHMP positive opinion)	TGA evaluation commenced	TGA approval	PBAC consideration			PBS listing
					First	Second	Third and subsequent	
Locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing therapy	18 May 2017	20 July 2017	28 February 2017	9 January 2018				
Locally advanced or metastatic urothelial carcinoma who have received platinum-containing chemotherapy	18 May 2017	20 July 2017	28 February 2017	9 January 2018	November 2017	July 2018		
Treatment of adult and paediatric patients with refractory primary mediastinal B-cell lymphoma, or who have relapsed after 2 or more prior lines of therapy	13 June 2018		31 January 2018	19 October 2018	November 2018			
Adjuvant treatment of patients with melanoma with lymph node involvement who have undergone complete resection				Pending (as at November 2018)	November 2018			
Treatment of patients with advanced microsatellite instability-high (MSI-H), including mismatch repair deficient (dMMR) cancer who have received prior therapy	23 May 2017				March 2019 (Colorectal cancer only)			

An additional 2 PBAC submissions were related to the Deed of Agreement and 2 were related to changes to the listing

*date accelerated FDA approval granted

Drug: atezolizumab [Tecentriq, Roche]

Bolded PBAC consideration dates = positive recommendation

Indication	FDA Approval	EMA approval (CHMP positive opinion)	TGA evaluation commenced	TGA approval	PBAC consideration			PBS listing
					First	Second	Third and subsequent	
Locally advanced or metastatic NSCLC with progression on or after prior chemotherapy.	18 October 2016	20 July 2017	31 July 2016	26 July 2017	November 2017			1 April 2018
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]					
In combination with paclitaxel and carboplatin, with or without bevacizumab, for the first-line treatment of patients with metastatic non-squamous NSCLC	6 December 2018		[REDACTED]		March 2019			

Drug: avelumab [Bavencio, Merck Serono]

Indication	FDA Approval	EMA approval (CHMP positive opinion)	TGA evaluation commenced	TGA approval	PBAC consideration			PBS listing
					First	Second	Third and subsequent	
Adults and paediatric patients 12 years and older with metastatic Merkel Cell Carcinoma (mMCC)	23 March 2017	20 July 2017	3 January 2017	2 January 2018	July 2018			

Drug: durvalumab [Imfinzi, AstraZeneca]

Indication	FDA Approval	EMA approval (CHMP positive opinion)	TGA evaluation commenced	TGA approval	PBAC consideration			PBS listing
					First	Second	Third and subsequent	
Treatment of patients with locally advanced, unresectable NSCLC whose disease has not progressed following platinum-based chemoradiation therapy.	16 February 2018	26 July 2018	29 September 2017	22 October 2018	November 2018			
Treatment of patients with locally advanced or metastatic urothelial carcinoma who: have disease progression during or following platinum-containing chemotherapy; have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.	1 May 2017		1 February 2017	2 October 2018				