IBM Watson Health

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 3/13/2020

PACKET: 1976

DRUG: Pembrolizumab

USE: Malignant mesothelioma of pleura; Previously treated

COMPENDIA TRANSPARENCY REQUIREMENTS	
1	Provide criteria used to evaluate/prioritize the request (therapy)
2	Disclose evidentiary materials reviewed or considered
3	Provide names of individuals who have substantively participated in the review or disposition of the request and disclose their potential direct or indirect conflicts of interest
4	Provide meeting minutes and records of votes for disposition of the request (therapy)

EVALUATION/PRIORITIZATION CRITERIA: C, L, R, S *to meet requirement 1

CODE	EVALUATION/PRIORITIZATION CRITERIA
A	Treatment represents an established standard of care or significant **advance** over current therapies
C	**Cancer** or cancer-related condition
E	Quantity and robustness of **evidence** for use support consideration
L	**Limited** alternative therapies exist for condition of interest
P	**Pediatric** condition
R	**Rare** disease
S	**Serious**, life-threatening condition

Note: a combination of codes may be applied to fully reflect points of consideration [eg, therapy may represent an advance in the treatment of a life-threatening condition with limited treatment alternatives (ASL)]

EVIDENCE CONSIDERED:

*to meet requirements 2 and 4

CITATION	STUDY-SPECIFIC COMMENTS	LITERATURE CODE
Alley, EW, Lopez, J, Santoro, A, et al: Clinical safety and activity of pembrolizumab in patients with malignant pleural mesothelioma (KEYNOTE-028): preliminary results from a non-randomised, open-label, phase 1b trial. Lancet Oncol May 2017; Vol 18, Issue 5; pp. 623-630.	This was a multicentre single-arm, phase 1b trial that assessed pembrolizumab therapy in previously treated patients with PD-L1-positive malignant pleural mesothelioma. There was low risk of bias associated with selection of cohort and assessment of outcome. All evaluable patients were included in the analyses. Median follow-up was 18.7 months (IQR, 9.4-24.2). There is an increased risk of bias associated with the lack of a control group in this study.	S
Desai, A, Karrison, T, Rose, B, et al: Phase II trial of pembrolizumab (NCT02399371) in previously-treated malignant mesothelioma (MM): final analysis. J Thorac Oncol Oct 01, 2018; Vol 13, Issue 10 Suppl; p. S339.		4
Kindler, H, Karrison, T, and Carol Tan, Y-H: Phase II trial of pembrolizumab in patients with malignant mesothelioma. J Thorac Oncol Jan 01, 2017; Vol 12, Issue 1; pp. S293-S294.		4
Metaxas, Y, Rivalland, G, Mauti, LA, et al: Pembrolizumab as palliative immunotherapy in malignant pleural mesothelioma. J Thorac Oncol Nov 2018; Vol 13, Issue 11; pp. 1784-1791.	This was a real-world data retrospective analysis that investigated the off-label use of pembrolizumab for malignant pleural mesothelioma in Swiss and Australian patients. There was low risk of bias associated with selection of cohort and high risk of bias for assessment of outcome. All patients were included in the analyses. Median follow-up was 9 months (IQR, 5-11 months). There is an increased risk of bias associated with the lack of a control group in this study.	S

Baas,P., Fennell,D., Kerr,K.M., et al: Malignant pleural mesothelioma: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol Sep 01, 2015; Vol 26 Supplement 5, pp. v31-v39.		2
Woolhouse, I, Bishop, L, Darlison, L, et al: British Thoracic Society guideline for the investigation and management of malignant pleural mesothelioma. Thorax Mar 2018; Vol 73 Suppl 1, pp. i1-i30.		2

Literature evaluation codes: S = Literature selected; 1 = Literature rejected = Topic not suitable for scope of content; 2 = Literature rejected = Does not add clinically significant new information; 3 = Literature rejected = Methodology flawed/Methodology limited and unacceptable; 4 = Other (review article, letter, commentary, or editorial)

CONTRIBUTORS:

*to meet requirement 3

PACKET PREPARATION	DISCLOSURES	EXPERT REVIEW	DISCLOSURES
Megan Smith	None		
Stacy LaClaire, PharmD	None		
Margi Schiefelbein, PA	None		
		John D Roberts	None
		Jeffrey Klein	None
		Richard LoCicero	Incyte Corporation Local PI for REVEAL. Study is a multicenter, non-interventional, non-randomized, prospective, observational study in an adult population for patients who have been diagnosed with clinically overt PV and are being followed in either community or academic medical centers in the US who will be enrolled over a 12-month period and observed for 36 months.

ASSIGNMENT OF RATINGS:
*to meet requirement 4

	EFFICACY	STRENGTH OF RECOMMENDATION	COMMENTS	STRENGTH OF EVIDENCE
IBM MICROMEDEX	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases		B
Jeffrey Klein	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases	The use of Pembrolizumab as 2nd line or greater in patients with malignant mesothelioma of the pleura is effective. Only a select patient type will benefit from this therapy. These patients need to have a high PD-L1 expression to show any benefit. The studies provided were small, but the medical options for previously treated patients are limited.	
John Roberts	Evidence is Inconclusive	Class IIb: Recommended, in Some Cases	Pembrolizumab has shown activity (partial and complete responses) against previously treated pleural malignant mesothelioma in a retrospective experience and an uncontrolled trial. Patients with PD-L1 positive tumors and ECOG Performance Status 0 or 1 may benefit. It is not recommended in other patients.	
Richard LoCicero	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases	Small observational studies have demonstrated clinical benefit for the palliative use of pembrolizumab in the treatment of pleural mesothelioma in previously treated patients. Response rates of 18% and 20% were observed without unexpected toxicity.	