TRUVEN HEALTH ANALYTICS
an IBM Company

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 12/7/2017

PACKET: 1611

DRUG: Nivolumab

USE: Malignant melanoma, adjuvant, following complete resection of Stage IIIB, IIIC, or IV (resected distant metastases) disease

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)]

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EVIDENCE CONSIDERED:

*to meet requirements 2 and 4

CITATION	STUDY-SPECIFIC COMMENTS	LITERATURE CODE
J. Weber et al. Adjuvant Nivolumab versus Ipilimumab in Resected Stage III or IV Melanoma. N Engl J Med. 2017 Sep 10. [Epub ahead of print]	Comments: This was a randomized, double-blind, phase 3 trial with 906 patients who were undergoing complete resection of stage IIIB, IIIC, or IV melanoma. The current study presented the interim analyses. At the time of this analysis, all the patients in the trial had finished treatment with a minimum follow-up of 18 months. Key bias criteria evaluated were (1) random sequence generation of randomization; (2) lack of allocation concealment, (3) lack of blinding, (4) incomplete accounting of patients and outcome events, and (5) selective outcome reporting bias. The study was at low risk of bias for these key criteria, and no additional biases were identified.	S

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
Felicia Gelsey, MS	None		
Stacy LaClaire, PharmD	None		
Catherine Sabatos, PharmD	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
MICROMEDEX	Effective	Class I: Recommended		B
John D Roberts	Effective	Class IIa: Recommended, In Most Cases	Nivolumab is more effective and better tolerated than ipilimumab, and presumably more effective than interferons, in the prevention of disease recurrence following resection of Stage IIIB, IIIC, or IV melanoma. It is likely, but at this time unknown, whether nivolumab improves overall survival. It also is unknown whether a strategy of delay until recurrence is apparent, which would spare the many surgically cured patients from adjuvant treatment, would be equally effective as adjuvant treatment.	N/A

Jeffrey Klein	Effective	Class I: Recommended	The use of Nivolumab to treat malignant melanoma patients following complete resection was shown to be quite effective. When compared to another agent in the study, nivolumab increased survival and prevented recurrence at a much higher level. In addition the adverse effects seen with nivolumab were much less than the competitor in the trial.	N/A
Richard LoCicero	Effective	Class I: Recommended	A randomized, double-blind, phase 3 trial demonstrated superior recurrence free survival with nivolumab, compared to ipilimumab, with lower toxicity	N/A