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COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 9/15/2017

PACKET: 1484

DRUG: Nivolumab

USE: Non-small cell lung cancer, metastatic or recurrent, PD-L1 expression, first-line treatment, with no EGFR or ALK tumor aberrations

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, 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
Carbone et al. First-Line Nivolumab in Stage IV or Recurrent Non–Small-Cell Lung Cancer. N Engl J Med 2017;376:2415-26.	Comments: This was a randomized, open-label, phase 3 trial. 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
Remon J, Besse B, Soria JC. Successes and failures: what did we learn from recent first-line treatment immunotherapy trials in non-small cell lung cancer? BMC Med. 2017 Mar 13;15(1):55.		4
Ramamurthy C1, Godwin JL1, Borghaei H. Immune Checkpoint Inhibitor Therapy: What Line of Therapy and How to Choose? Curr Treat Options Oncol. 2017 Jun;18(6):33. doi: 10.1007/s11864-017-0476-y.		4
Hannah N, et al: Systemic Therapy for Stage IV Non–Small-Cell Lung Cancer: American Society of Clinical Oncology Clinical Practice Guideline Update. DOI: 10.1200/JCO.2017.74.6065 Journal of Clinical Oncology - published online before print August 14, 2017		4

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)

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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	Evidence Favors Efficacy	Class IIb: Recommended, In Some Cases		B
John D Roberts	Evidence Favors Efficacy	Class IIb: Recommended, In Some Cases	In a problematic trial, Nivolumab had similar effectiveness and was better tolerated than standard platinum-based chemotherapy in patients with PD-L1 expression of 5% or greater. Problems included: the trial was designed to demonstrate superiority of nivolumab, not non-inferiority; a minority of enrolled patients were ultimately eligible for randomization; despite randomization, a number of prognostic factors were poorly balanced; the primary endpoint was progression free survival by RECIST 1.1, which does not recognize radiographic pseudo-progression that is frequently seen with nivolumab and similar agents; extensive cross-over following progression of disease; omission of outcomes in patients with tumors of 1% - <5% PD-L1 expression.	N/A

Jeffrey Klein	Evidence Favors Efficacy	Class IIb: Recommended, In Some Cases	The use of Nivolumab as a first line single agent for NSCLC showed a similar type of efficacy as cisplatin based combination therapy. Less adverse effects with the use of nivolumab was the key factor for favoring its use, though cost and frequency of therapy needs to be considered.	N/A
Richard LoCicero	Ineffective	Class III: Not Recommended	Nivolumab was not associated with a longer progression-free survival or overall survival compared with platinum-based chemotherapy. Its use is not established in this setting.	N/A