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COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 7/29/16

PACKET: 1347

DRUG: Atezolizumab

USE: Non-small cell lung cancer, advanced disease, 2nd or 3rd line after failure of platinum-based chemotherapy

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, 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
Fehrenbacher,L., Spira,A., Ballinger,M., et al: Atezolizumab versus docetaxel for patients with previously treated non-small-cell lung cancer (POPLAR): a multicentre, open-label, phase 2 randomised controlled trial. Lancet Mar 09, 2016; Vol Epub, p. Epub.	Comments: This was an open-label, multicenter, phase 2 randomized 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; however there may be high risk of bias for assessing subjective endpoints due to the open-label design.	S
Besse,B., Johnson,M., Jänne,P.A., et al: Phase II, single-arm trial (BIRCH) of atezolizumab as first-line or subsequent therapy for locally advanced or metastatic PD-L1-selected non-small cell lung cancer (NSCLC). European Journal of Cancer 2015; Vol 51 SUPPL. 3, pp. S717-S718.	Abstract	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)

CONTRIBUTORS:

*to meet requirement 3

PACKET PREPARATION	DISCLOSURES	EXPERT REVIEW	DISCLOSURES
Felicia Gelsey, MS	None		
Stacy LaClaire, PharmD	None		
Catherine Sabatos, PharmD	None		
		Jeffrey Klein	None
		John Roberts	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
Jeffrey Klein	Evidence Favors Efficacy	Class IIa: Recommended, In Most Cases	The use of atezolizumab as a 2nd or 3rd line treatment in nsclc pts who have failed platinum based therapy showed an increase overall survival when compared to docetaxel in a head to head trial. It was well tolerated with limited adverse effects. The trial was not large and pts need to have pdl1 expression to achieve the best result (this may may limit its use).	N/A

John Roberts	Effective	Class I: Recommended	In this moderate sized phase II trial, atezolizumab was more effective and better tolerated than docetaxel as second or third line treatment in PS 0-1 patients with advanced non-small cell lung cancer. Although differences in response rate or disease free survival were not impressive, overall survival was significantly improved. Further, inspection of the survival plots suggests that benefit may be very long-lasting, something that is not captured in standard statistical terms. These results are consistent with other trials of immune checkpoint inhibition in non-small cell lung cancer. The results reflect both the modest but real effectiveness of these agents and the ineffectiveness of docetaxel, which is of dubious value for the usual patient. Predictive markers show better outcomes with higher levels of PD-L1 expression in tumor cells and/ or tumor-infiltrating lymphocytes, but lack of benefit in the absence of PD-L1 was not demonstrated.	N/A
Richard LoCicero	Effective	Class I: Recommended	Atezolizumab has demonstrated superior efficacy compared with docetaxel with less toxicity in this population.	N/A