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COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 4/15/16

PACKET: 1282

DRUG: Bevacizumab

USE: Mesothelioma

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: A, C, 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
Zalcman,G., Mazieres,J., Margery,J., et al: Bevacizumab for newly diagnosed pleural mesothelioma in the Mesothelioma Avastin Cisplatin Pemetrexed Study (MAPS): A randomised, controlled, open-label, phase 3 trial. The Lancet 2015	This was a multicenter, open-label, randomized, phase 3 trial. Overall, this study had a crucial limitation for one criterion sufficient to lower ones confidence in the estimate effect. There was potentially high risk of bias for subjective outcomes due to the open-label design. This trial that did not use independent reviewers or assessors. There was low risk of bias associated with random sequence generation, allocation concealment, incomplete accounting of patients and outcome events, and selective outcome reporting.	S
Kindler,H.L., Karrison,T.G., Gandara,D.R., et al: Multicenter, double-blind, placebo-controlled, randomized phase II trial of gemcitabine/cisplatin plus bevacizumab or placebo in patients with malignant mesothelioma. J Clin Oncol Jul 10, 2012; Vol 30, Issue 20; pp. 2509-2515.	This was a double-blind, randomized, placebo-controlled, phase II trial. Key risk of 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.	2
Kondola,S., Manners,D., and Nowak,A.K.: Malignant pleural mesothelioma: an update on diagnosis and treatment options. Ther Adv Respir Dis Feb 12, 2016		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 D 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.

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ASSIGNMENT OF RATINGS:

*to meet requirement 4

	EFFICACY	STRENGTH OF RECOMMENDATION	COMMENTS	STRENGTH OF EVIDENCE
MICROMEDEX	Effective	Class IIa: Recommended, In Most Cases		B
Jeffrey Klein	Effective	Class IIa: Recommended, In Most Cases	The addition of Bevacizumab to pemetrexed and cisplatin showed a significant increase in overall survival than the group that did not receive it in this 6 year study. Adverse effects were slightly more evident but seem to be very manageable. These pts had to meet a vast amount of criteria to be included in the study. Among such requirements were being newly diagnosed, not eligible for surgery, pts who didn't have various bleeding disorders, and this being their first line treatment.	N/A
John D Roberts	Effective	Class IIa: Recommended, In Most Cases	In a generally well designed and conducted trial, addition of bevacizumab to a standard regimen of pemetrexed and cisplatin modestly improved overall survival with acceptable additional toxicity. Patients with significant cardiovascular disease were excluded, and an observed increase in hypertension and thrombotic events in patients (without cardiovascular disease) receiving bevacizumab suggests that this exclusion was wise and appropriate for practice. Patients with Performance Status 2 were eligible and did as well as other patients, but only a very small number of such patients were enrolled. This suggests that investigators offered enrollment only to selected patients with PS 2; clinicians should consider this when making recommendations to such patients.	N/A
Richard LoCicero	Effective	Class I: Recommended	The addition of bevacizumab to the FDA-approved regimen of pemetrexed and cisplatin was associated with an improvement in overall survival in a randomized, phase III trial.	N/A