TRUVEN HEALTH ANALYTICS
an IBM Company

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 12/14/2018

PACKET: 1810

DRUG: Bevacizumab

USE: Extensive stage small cell lung cancer, First-line, in combination with 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, E, 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
Tiseo,M., Boni,L., Ambrosio,F., et al: Italian, multicenter, phase III, randomized study of cisplatin plus etoposide with or without bevacizumab as first-line treatment in extensive-disease small-cell lung cancer: The GOIRC-AIFA FARM6PMFJM Trial. J Clin Oncol Apr 20, 2017; Vol 35, Issue 12; pp. 1281-1287.	Comments: This was a multicenter, open-label, randomized controlled phase III trial performed at 29 Italian centers. 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 potentially high risk of bias for subjective outcomes due to the open label design.	S
Pujol,J.L., Lavole,A., Quoix,E., et al: Randomized phase II-III study of bevacizumab in combination with chemotherapy in previously untreated extensive small-cell lung cancer: results from the IFCT-0802 trialdagger. Ann Oncol May 2015; Vol 26, Issue 5; pp. 908-914.	Comments: This was a French intergroup, prospective, randomized phase II–III study of Bev in EDSCLC patients after response to chemotherapy. This open randomized study was planned in two phases: phases II and III. The response rate was used as primary end point in phase II and overall survival (OS) in phase III. Overall, this study was at low risk of biases associated with lack of blinding, incomplete accounting of patients and outcome events, and selective outcome reporting. The risk of bias associated with poor random sequence generation and allocation concealment was unclear and not discussed in the paper. There may be potentially high risk of bias for subjective outcomes due to the open label design.	S
Spigel,D.R., Townley,P.M., Waterhouse,D.M., et al: Randomized phase II study of bevacizumab in combination with chemotherapy in previously untreated extensive-stage small-cell lung cancer: results from the SALUTE trial. Journal of Clinical Oncology Jun 01, 2011; Vol 29, Issue 16; pp. 2215-2222.	Comments: SALUTE (A Study of Bevacizumab in Previously Untreated Extensive-Stage Small Cell Lung Cancer), was a placebo-controlled, double-blind, randomized multicenter phase II clinical trial. Overall, this study was at low risk of biases associated with lack of blinding, incomplete accounting of patients and outcome events, and selective outcome reporting. The risk of bias associated with poor random sequence generation and allocation concealment was unclear and not discussed in the paper.	S

Tiseo,M., Boni,L., Ambrosio,F., et al: Italian multicenter phase III randomized study of cisplatin-etoposide with or without bevacizumab as first-line treatment in extensive stage small cell lung cancer: treatment rationale and protocol design of the GOIRC-AIFA FARM6PMFJM trial. Clin Lung Cancer Jan 2015; Vol 16, Issue 1; pp. 67-70.		2
Zhu,Y.J., Zhang,H.B., Liu,Y.H., et al: Meta-analysis of the role of bevacizumab in extensive stage small cell lung cancer. Oncol Lett Jul 2017; Vol 14, Issue 1; pp. 655-664.		3

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	Ineffective	Class III: Not Recommended		A
John D Roberts	Ineffective	Class III: Not Recommended	In 3 randomized trials addition of bevacizumab to standard treatments did not improve overall survival and was associated with a mild to moderate increase in toxicity.	N/A
Jeffrey Klein	Ineffective	Class III: Not Recommended	The addition of Bevacizumab to a chemotherapy regimen to treat first line small cell lung cancer patients did not show any signifiant benefits. Progression free survival was minimal and overall survival was negligible. In addition patients were subjected to high grade adverse effects.	N/A
Richard LoCicero	Ineffective	Class III: Not Recommended	The addition of bevacizumab to chemotherapy does not improve overall survival in the treatment of extensive stage small cell lung cancer.	N/A