TRUVEN HEALTH ANALYTICS

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: **JUNE 2015**

PACKET: **1225**

DRUG: **Ramucirumab**

INDICATION: **METASTATIC BREAST CANCER, HER2-NEGATIVE, FIRST-LINE, IN COMBINATION WITH DOCETAXEL**

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 *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)]

©2012 Truven Health Analytics Inc. All rights reserved.

TRUVEN HEALTH ANALYTICS

EVIDENCE CONSIDERED:

*to meet requirements 2 and 4

CITATION	STUDY-SPECIFIC COMMENTS	LITERATURE CODE
Mackey, J et al. Primary Results of ROSE/TRIO-12, a Randomized Placebo-Controlled Phase III Trial Evaluating the Addition of Ramucirumab to First-Line Docetaxel Chemotherapy in Metastatic Breast Cancer. J Clin Oncol 2015 33:141-148.	This was a multinational, placebo-controlled, randomized phase III 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 random sequence generation and allocation concealment was unclear and not discussed in the paper.	S
Mackey,J., Gelmon,K., Martin,M., et al: TRIO-012: a multicenter, multinational, randomized, double-blind phase III study of IMC-1121B plus docetaxel versus placebo plus docetaxel in previously untreated patients with HER2-negative, unresectable, locally recurrent or metastatic breast cancer. Clin Breast Cancer Nov 2009; Vol 9, Issue 4; pp. 258-261.		2
MacKey,J.R., Ramos-Vazquez,M., Lipatov,O., et al: Primary results of ROSE/TRIO-12, a randomized placebo controlled phase III trial evaluating the addition of ramucirumab to first-line docetaxel chemotherapy in metastatic breast cancer. Cancer Research Dec 15, 2013; Vol 73, Issue 24 SUPPL. 1. Date of Publication; p. 1.		2

©2012 Truven Health Analytics Inc. All rights reserved.

Vahdat,L.T., Miller,K., Sparano,J.A., et al: Randomized phase II study of capecitabine with or without ramucirumab (IMC-1121B) or IMC-18F1 in patients with unresectable, locally advanced or metastatic breast cancer (mBC) previously treated with anthracycline and taxane therapy (CP20-0903/NCT01234402). Journal of Clinical Oncology 2011; Vol 29, Issue 15 SUPPL. 1.	This is an abstract.	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)

©2012 Truven Health Analytics Inc. All rights reserved.

TRUVEN HEALTH ANALYTICS

CONTRIBUTORS:

*to meet requirement 3

PACKET PREPARATION	DISCLOSURES	EXPERT REVIEW	DISCLOSURES
Margi Schiefelbein, PA	None	Keith Thompson, MD	None
Stacy LaClaire, PharmD	None	Edward Balaban, DO	None
Felicia Gelsey, MS	None	James Liebmann, MD	None
		Thomas Marsland, MD	None
		Jeffrey A. Bubis, DO	None

ASSIGNMENT OF RATINGS:

*to meet requirement 4

	EFFICACY	STRENGTH OF RECOMMENDATION	COMMENTS	STRENGTH OF EVIDENCE
MICROMEDEX	---	---		B
Keith Thompson, MD	Ineffective	Class III: Not Recommended	None	N/A
Edward Balaban, DO	Ineffective	Class III: Not Recommended	PFS better, but not statistically significant change; overall survival not changed – seems to have a pretty broad side effect profile.	N/A
James Liebmann, MD	Ineffective	Class III: Not Recommended	The ROSE/TRIO-12 trial was a large, well designed trial that showed that the addition of ramucirumab to docetaxel caused more side effects, but produced no benefits to patients with metastatic HER2 negative breast cancer. As the authors stated in their discussion, ramucirumab “failed to meaningfully improve important clinical outcomes.” It cannot be endorsed for this indication.	N/A
Thomas Marsland, MD	Ineffective	Class III: Not Recommended	Large randomized well done trial did not show any benefit with survival of this drug in breast cancer. This is consistent with other anti VEGF treatments.	N/A

©2012 Truven Health Analytics Inc. All rights reserved.

Jeffrey A. Bubis, DO	Ineffective	Class lll: Not Recommended	No change in survival.	N/A

©2012 Truven Health Analytics Inc. All rights reserved.