TRUVEN HEALTH ANALYTICS

COMPENDIA TRANSPARENCY TRACKING FORM

DRUG: Bevacizumab

INDICATION: Metastatic breast cancer, HER2-negative, as second-line therapy in combination with other 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**
*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)]

TRUVEN HEALTH ANALYTICS

EVIDENCE CONSIDERED:

*to meet requirements 2 and 4

CITATION	STUDY-SPECIFIC COMMENTS	LITERATURE CODE
Brufsky A., et al. RIBBON-2: a randomized, double-blind, placebo-controlled, phase III trial evaluating the efficacy and safety of bevacizumab in combination with chemotherapy for second-line treatment of HER2-negative metastatic breast cancer. San Antonio Breast Cancer Symposium 2009 slide presentation and abstract.	Study methodology comments: This was a rigorously designed randomized, double-blind, placebo-controlled, phase III trial with many strengths. Additional strengths of the study included 1) defined primary and secondary outcomes; 2) analyzed the intent-to-treat population; 3) had both inclusion and exclusion criteria; 4) presented 95% confidence intervals; 5) compared baseline characteristics of groups; 6) controlled the effect of potential confounding factors on study outcomes; 7) conducted a power analysis; and 8) made statistical adjustments to preserve the type I error rate. Weaknesses included 1) possible selection bias since subjects were not recruited in a random or consecutive manner; 2) did not discuss method of randomization; and 3) did not define tumor response.	S
Bevacizumab combined with taxanes in second-line or more for metastatic breast cancer: Efficacy and predictive factors of response. ASCO abstract 2009.		2
Gonzalez-Martin, A., et al. Bevacizumab in combination with chemotherapy (CT) in previously treated metastatic breast cancer (MBC) patients (Publish Only). 2009 Breast Cancer Symposium Abstract		3
Robert N, et al. Phase III Studies of Bevacizumab (B) in Combination with Chemotherapy in Patients with HER2-Negative Metastatic Breast Cancer (MBC): Summary of Selected Adverse Events. 2009 abstract.		3

Tan WW, et al. N0539 Phase II Trial of Fulvstrant and Bevacizumab in Patients with Metastatic Breast Cancer Previously Treated with an Aromatase Inhibitor: A North Central Cancer Treatment Group Trial. 2009 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)

TRUVEN HEALTH ANALYTICS

CONTRIBUTORS:

*to meet requirement 3

PACKET PREPARATION	DISCLOSURES	EXPERT REVIEW	DISCLOSURES
Amy Hemstreet, PharmD	None	Thomas McNeil Beck, MD	None
Stacy LaClaire, PharmD	None	Susan Goodin, PharmD	None
Felicia Gelsey, MS	None	Gerald J. Robbins, MD	None
		Keith A. Thompson, MD	None
		John M. Valgus, PharmD	None

ASSIGNMENT OF RATINGS:

*to meet requirement 4

	EFFICACY	STRENGTH OF RECOMMENDATION	COMMENTS	STRENGTH OF EVIDENCE
MICROMEDEX	---	---		B
Thomas McNeil Beck, MD	Evidence is Inconclusive	Class III: Not Recommended	No survival benefit.	N/A
Susan Goodin, PharmD	Evidence Favors Efficacy	Class IIa: Recommended, In Most Cases	None	N/A
Gerald J. Robbins, MD	Evidence Favors Efficacy	Class IIb: Recommended, In Some Cases	Taxanes only chemo tx that resulted in definite PFS advantage. This is frequently a population of younger women where PFS is important; and as only a 2nd line therapy in a cancer with multiple effective therapies would not expect a significant change in OS. Would prefer to wait for full publication rather than abstract. Would limit indication to Taxanes unless more data available.	N/A
Keith A. Thompson, MD	Evidence Favors Efficacy	Class IIb: Recommended, In Some Cases	None	N/A

John M. Valgus, PharmD	Evidence Favors Efficacy	Class IIa: Recommended, In Most Cases	Initial data is very positive and did reach primary objective. Survival data still immature so cannot routinely recommend.	N/A