TRUVEN HEALTH ANALYTICS

COMPENDIA TRANSPARENCY TRACKING FORM

DRUG: Bevacizumab

INDICATION: Gastric cancer, advanced, first-line therapy in combination with fluoropyrimidine-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, 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
Ohtsu,A., et al: Bevacizumab in Combination With Chemotherapy As First-Line Therapy in Advanced Gastric Cancer: A Randomized, Double-Blind, Placebo-Controlled Phase III Study. Journal of Clinical Oncology Oct 20, 2011; Vol 29, Issue 30; pp. 3968-3976.	Study methodology comments: 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, except allocation concealment which was not discussed.	S
Shah,M.A., Ilson,D., and Kelsen,D.P.: Thromboembolic events in gastric cancer: High incidence in patients receiving irinotecan- and bevacizumab-based therapy. Journal of Clinical Oncology Apr 10, 2005; Vol 23, Issue 11; pp. 2574-2576.		4
Okines,A., Verheij,M., Allum,W., et al: Gastric cancer: ESMO clinical practice guidelines for diagnosis, treatment and follow-up. Annals of Oncology May 2010; Vol 21, Issue SUPPL. 5; pp. v50-v54.		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)

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CONTRIBUTORS:
*to meet requirement 3

PACKET PREPARATION	DISCLOSURES	EXPERT REVIEW	DISCLOSURES
Margi Schiefelbein, PA	None	Edward P. Balaban, DO	None
Stacy LaClaire, PharmD	None	James E. Liebmann, MD	None
Felicia Gelsey, MS	None	Jeffrey A. Bubis, DO	Other payments: Dendreon
		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
Edward P. Balaban, DO	Evidence is inconclusive	Class IIb - Recommended, In Some Cases	Strength of recommendation has to be IIb – data is too scant to comment further. Evidence is inconclusive for same reason. Like to see more data. Intriguing initial experience.	N/A

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James E. Liebmann, MD	Evidence is inconclusive	Class III - Not Recommended	There is a single study to support this indication. While the trial is well done, it shows no improvement in overall survival with the addition of Bevacizumab to Cisplatin and Capecitabine. It is true that response rates and progression free survival were higher on the Bevacizumab arm and toxicity from Bev was remarkably mild (only 6% hypertension, no increase in chemotherapy-associated AEs). However, the lack of a survival benefit makes it hard to be enthusiastic about the addition of Bevacizumab to this chemotherapy regimen.	N/A
Jeffrey A. Bubis, DO	Evidence is inconclusive	Class III - Not Recommended	Lack of os benefit. RR & PFS varied based on geography. Increases toxicity, but not outcomes and better alternatives available.	N/A
Keith A. Thompson, MD	Evidence favors efficacy	Class IIb - Recommended, In Some Cases	None	N/A
John M. Valgus, PharmD	Evidence is inconclusive	Class IIb - Recommended, In Some Cases	Although no statistical improvement in os, there was a trend with a 2month difference in os. PFS was improved and sub group analysis provided possible groups to further explore this treatment.	N/A

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