TRUVEN HEALTH ANALYTICS

COMPENDIA TRANSPARENCY TRACKING FORM

DRUG: Bevacizumab

INDICATION: Ovarian cancer, advanced, first-line therapy in combination with carboplatin and paclitaxel

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, 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
Burger,R.A., et al: Incorporation of bevacizumab in the primary treatment of ovarian cancer. N Engl J Med Dec 29, 2011; Vol 365, Issue 26; pp. 2473-2483.	Study methodology comments: Overall, this study was at low risk for all key criteria which included lack of blinding and allocation concealment, incomplete accounting of patients and outcome events, and selective outcome reporting.	S
Perren,T.J., et al: A phase 3 trial of bevacizumab in ovarian cancer. New England Journal of Medicine Dec 29, 2011; Vol 365, Issue 26; pp. 2484-2496.	Study methodology comments: Overall, this study was at low risk for all key criteria which included lack of blinding and allocation concealment, incomplete accounting of patients and outcome events, and selective outcome reporting.	S
Burger,R., Brady,M., Bookman,M., et al: Safety and Subgroup Efficacy Analyses in Gog218, A Phase Iii Trial of Bevacizumab (Bev) in the Primary Treatment of Advanced Epithelial Ovarian Cancer (Eoc), Primary Peritoneal Cancer (Ppc) Or Fallopian Tube Cancer (Ftc): A Gynecologic Oncology Group Study. Annals of Oncology Oct 2010; Vol 21, pp. 307-307		2
Burger,R.A., Brady,M.F., Rhee,J., et al: Independent radiologic review of GOG218, a phase III trial of bevacizumab (BEV) in the primary treatment of advanced epithelial ovarian (EOC), primary peritoneal (PPC) or Fallopian tube cancer (FTC). Journal of Clinical Oncology 2011; Vol 29, Issue 15 SUPPL		2

Gonzalez-Martin,A., et al: Front-line Bevacizumab (BEV) Combined With Weekly Paclitaxel (wPAC) and Carboplatin (C) for Ovarian Cancer (OC): Safety Results From the Concurrent Chemotherapy (CT) Phase of the OCTAVia Study. European Journal of Cancer Sep 2011; Vol 47, pp. S528-S528.		3
Cohn,D., et al: At what cost does a potential survival advantage of bevacizumab make sense for the primary treatment of ovarian cancer? A cost-effectiveness analysis. Gynecologic Oncology Mar 2010; Vol 116, Issue 3; pp. S12-S13.		3
Herzog,T., Rose,P., Braly,P., et al: Preliminary safety results of TEACO, a phase 2 trial of oxaliplatin, docetaxel and bevacizumab as first-line therapy for advanced cancer of the ovary, peritoneum and fallopian tube. Gynecologic Oncology Feb 2009; Vol 112, Issue 2; pp. S27-S27		3
Kristensen,G., Perren,T., Qian,W., et al: Result of interim analysis of overall survival in the GCIG ICON7 phase III randomized trial of bevacizumab in women with newly diagnosed ovarian cancer. Journal of Clinical Oncology 2011; Vol 29, Issue 18 SUPPL. 1		3

Perren,T., Swart,A., Pfisterer,J., et al: A Phase Iii Randomised Gynaecologic Cancer Intergroup Trial of Concurrent Bevacizumab and Chemotherapy Followed by Maintenance Bevacizumab, Versus Chemotherapy Alone in Women with Newly Diagnosed Epithelial Ovarian (Eoc), Primary Peritoneal (Ppc) Or Fallopian Tube Cancer (Ftc). Annals of Oncology Oct 2010; Vol 21, pp. 2-3		2
Rose,P., Drake,R., Braly,P., et al: Preliminary results of a phase II study of oxaliplatin, docetaxel, and bevacizumab as first-line therapy of advanced cancer of the ovary, peritoneum, and fallopian tube. Journal of Clinical Oncology May 20, 2009; Vol 27, Issue 15; p. 1		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
Margi Schiefelbein, PA	None	Edward P. Balaban, DO	None
Stacy LaClaire, PharmD	None	James E. Liebmann, MD	None
Felicia Gelsey, MS	None	Jeffrey F. Patton, MD	None
		Gerald J. Robbins, MD	None
		Keith A. Thompson, MD	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	It's not clear that Avastin offers any benefit when combined with Carbo/Taxol upfront. It may instead demonstrate its impact as a maintenance treatment following Carbo/Taxol.	N/A

James E. Liebmann, MD	Evidence is inconclusive	Class III - Not Recommended	The two trials of similar, but not identical, regimens of adjuvant treatment of ovarian cancers showed modest (1.7 and 1.9 months) improvement in PFS, but no difference in OS in patients who received Bevacizumab (Bev). The OS data are not mature in the ICON trial. While the OS data are mature in the GOG trial, there is no information on the use of Bev at relapse in the Gog patients. Hence, Bev may have no impact on survival and neither trial showed any improvement in quality of life with Bev.	N/A
Jeffrey F. Patton, MD	Effective	Class IIa - Recommended, In Most Cases	Met primary end point in 2 well designed randomized trials.	N/A
Gerald J. Robbins, MD	Effective	Class IIa - Recommended, In Most Cases	1.Significant PFS. 2. Prior studies document efficacy in other ovarian cancer settings. 3. Since OS not increased after 24 months, but a reproducible increase in DFS, it should be available for patients that accept toxicity profile and see value in the DFS benefit.	N/A
Keith A. Thompson, MD	Evidence favors efficacy	Class IIb - Recommended, In Some Cases	For some, improvement in PFS is enough to add.	N/A