TRUVEN HEALTH ANALYTICS™

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: **November 2015**

PACKET: **1256**

DRUG: **Paclitaxel protein-bound**

USE: **Malignant tumor of ovary, recurrent, platinum-resistant**

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, L, 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
Tillmanns,T.D., et al: Phase II clinical trial of bevacizumab with albumin-bound paclitaxel in patients with recurrent, platinum-resistant primary epithelial ovarian or primary peritoneal carcinoma. Gynecologic Oncology Sep 05, 2012; pp. 1	Overall comments: This was an open-label, phase ll, single-arm trial. The study has some important problems that include lack of a control group and subjective outcomes were assessed in an open-label manner. The study is judged to be at serious risk of bias in at least one domain but not at critical risk of bias in any domain.	S
Coleman,R.L., et al: A phase II evaluation of nanoparticle, albumin-bound (nab) paclitaxel in the treatment of recurrent or persistent platinum-resistant ovarian, fallopian tube, or primary peritoneal cancer: a Gynecologic Oncology Group study. Gynecol Oncol Jul 2011; Vol 122, Issue 1; pp. 111-115.	Overall comments: This was an open-label, phase ll, single-arm trial. The study has some important problems that include lack of a control group and subjective outcomes were assessed in an open-label manner. The study is judged to be at serious risk of bias in at least one domain but not at critical risk of bias in any domain.	S
Teneriello,M.G., et al: Phase II evaluation of nanoparticle albumin-bound paclitaxel in platinum-sensitive patients with recurrent ovarian, peritoneal, or fallopian tube cancer. J Clin Oncol Mar 20, 2009; Vol 27, Issue 9; pp. 1426-1431.	Overall comments: This was an open-label, phase ll, single-arm trial. The study has some important problems that include lack of a control group and subjective outcomes were assessed in an open-label manner. The study is judged to be at serious risk of bias in at least one domain but not at critical risk of bias in any domain.	1
Benigno,B.B., et al: A phase II nonrandomized study of nab-paclitaxel plus carboplatin in patients with recurrent platinum-sensitive ovarian or primary peritoneal cancer. Journal of Clinical Oncology 2010; Vol 28, Issue 15 SUPPL; p. 1.	Abstract	4

Kudlowitz,D. and Muggia,F.: Nanoparticle albumin-bound paclitaxel (nab-paclitaxel): Extending its indications. Expert Opinion on Drug Safety Jun 2014; Vol 13, Issue 6; pp. 681-685.		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)

CONTRIBUTORS:

*to meet requirement 3

PACKET PREPARATION	DISCLOSURES	EXPERT REVIEW	DISCLOSURES
Felicia Gelsey, MS	None	Edward Balaban, DO	None
Stacy LaClaire, PharmD	None	Jeffrey A. Bubis, DO	None
Catherine Sabatos, PharmD	None	Keith Thompson, MD	None

ASSIGNMENT OF RATINGS:

*to meet requirement 4

	EFFICACY	STRENGTH OF RECOMMENDATION	COMMENTS	STRENGTH OF EVIDENCE
MICROMEDEX	---	---		B
Edward Balaban, DO	Evidence Favors Efficacy	Class IIb: Recommended, In Some Cases	Efficacious enough in Phase II Trials, and tolerated enough that this agent could be recommended in some cases. Will need further study to obtain a different recommendation rating.	N/A
Jeffrey A. Bubis, DO	Evidence is Inconlusive	Class IIb: Recommended, In Some Cases	Consideration of this agent can be given in patients with an allergy to generic paclitaxel, but the data would not indicate that it should be a standard agent in the treatment of patients with ovarian cancer.	N/A
Keith Thompson, MD	Evidence Favors Efficacy	Class IIb: Recommended, In Some Cases	None	N/A