TRUVEN HEALTH ANALYTICS

COMPENDIA TRANSPARENCY TRACKING FORM

DRUG: DOXORUBICIN HYDROCHLORIDE LIPOSOME

INDICATION: Malignant tumor of ovary, first-line therapy, in combination therapy

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)]

TRUVEN HEALTH ANALYTICS

EVIDENCE CONSIDERED:

*to meet requirements 2 and 4

CITATION	STUDY-SPECIFIC COMMENTS	LITERATURE CODE
Lawrie,T.A., Rabbie,R., Thoma,C., et al: Pegylated liposomal doxorubicin for first-line treatment of epithelial ovarian cancer. Cochrane.Database.Syst.Rev. 2013; Vol 10, p. CD010482.	This systematic review (SR) met all the criteria deemed critical to the quality of an SR. The studies included in the SR were at low risk of bias for random sequence generation, allocation concealment, blinding, and selective outcome reporting. In general, the evidence was considered to be of high quality. The SR consisted of two RCTs but a meta-analysis was not conducted.	S
Bookman,M.A., Brady,M.F., McGuire,W.P., et al: Evaluation of new platinum-based treatment regimens in advanced-stage ovarian cancer: a Phase III Trial of the Gynecologic Cancer Intergroup. J Clin Oncol Mar 20, 2009; Vol 27, Issue 9; pp. 1419-1425.		
Pignata,S., Scambia,G., Ferrandina,G., et al: Carboplatin plus paclitaxel versus carboplatin plus pegylated liposomal doxorubicin as first-line treatment for patients with ovarian cancer: The. Journal of Clinical Oncology Sep 20, 2011; Vol 29, Issue 27; pp. 3628-3635.		
Pignata,S., Scambia,G., Savarese,A., et al: Carboplatin and pegylated liposomal doxorubicin for advanced ovarian cancer: Preliminary activity results of the MITO-2 phase III trial. Oncology Dec 2009; Vol 76, Issue 1; pp. 49-54.		
Cherchi,P.L., Bagella,M.P., Campiglio,A., et al: Fist line chemotherapy in advanced ovarian cancer: a comparison of three therapeutic regimes. Eur.J Gynaecol.Oncol. 1990; Vol 11, Issue 6; pp. 453-456.		3

Potamianou,A., Androulakis,N., Papakotoulas,P., et al: Sequential combination of paclitaxel-carboplatin and paclitaxel-liposomal doxorubicin as a first-line treatment in patients with ovarian cancer: A multicenter phase II trial. Oncology Nov 2005; Vol 69, Issue 4; pp. 348-353.		3
Ferrandina,G., Corrado,G., Licameli,A., et al: Pegylated liposomal doxorubicin in the management of ovarian cancer. Ther Clin Risk Manag. 2010; Vol 6, pp. 463-483.		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)

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	John M. Valgus, PharmD	None
Felicia Gelsey, MS	None	James E. Liebmann, MD	None
		Jeffrey A. Bubis, DO	Other payments: Dendreon
		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 favors efficacy	Class IIb - Recommended, In Some Cases	Pegylated doxorubicin (PLD) + carbo outcome risk is not inferior to standard paclitaxel/carbo. Side effect profile does better enough that it could be a reasonable alternative (if in those with pre-existing neuropathy.	N/A
John M. Valgus, PharmD	Evidence favors efficacy	Class IIa - Recommended, In Most Cases	One could recommend liposomal doxorubicin in combination with carboplatin as an alternative first- line therapy to paclitaxel carboplatin based on the results of this meta-analysis (same PFS and OS but different toxicity profile). One would not recommend the three drug combination though.	N/A

James E. Liebmann, MD	Evidence is inconclusive	Class IIb - Recommended, In Some Cases	Liposomal doxorubicin can only be considered in this setting in patients in whom there is a great desire to avoid peripheral neuropathy or alopecia. The drug should only be given with carboplatin – addition of the drug to the "standard" regimen of carboplatin and paclitaxel only added toxicity and so such "triplet" therapy should not be given. Patients and physicians who choose to receive liposomal doxorubicin in place of paclitaxel, should be aware of the higher risk of anemia and neutropenia. Finally, patients should be aware that a dose of liposomal doxorubicin will be considerably more expensive than a dose of paclitaxel. (Jan, 2014 Medicare ASP lipodox – 10mg = $498.26; paclitaxel – 30mg = $4.38; for a patient with a BSA of 1.7, approximate purchase prices of the drugs given at 30mg/m2 and 175 mg/m2, respectively, would be $2500 for lipodox and $440 for paclitaxel.) A patient with correspondingly higher insurance co-pay may wish to take this into account.	N/A
Jeffrey A. Bubis, DO	Ineffective	Class III - Not Recommended	No more effective and more toxic than the control arm.	N/A
Keith A. Thompson, MD	Evidence favors efficacy	Class IIb - Recommended, In Some Cases	None	N/A