TRUVEN HEALTH ANALYTICS

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: **MAY 2015**

PACKET: **1131**

DRUG: **Vinorelbine Tartrate**

INDICATION: **Malignant pleural mesothelioma**

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
Muers,MF, Stephens,RJ, Fisher,P, et al: Active symptom control with or without chemotherapy in the treatment of patients with malignant pleural mesothelioma (MS01): a multicentre randomised trial. Lancet May 17, 2008; Vol 371, Issue 9625; pp. 1685-1694.	This was a randomized-controlled trial. Due to slow accrual, the trial was stopped early and didn't meet the original planned sample size of 840 patients. The two chemo arms were combined and compared to active symptom control. With a target of 420 patients, there was 76% power to detect a 3 month benefit in OS with chemo. This study was at low risk of bias associated with allocation concealment, lack of blinding, incomplete accounting of patients and outcome events, and selective outcome reporting. The risk of bias associated with random sequence generation was unclear and not discussed in the paper.	S
Stebbing,J.: The efficacy and safety of weekly vinorelbine in relapsed malignant pleural mesothelioma. Lung Cancer Jan 2009; Vol 63, Issue 1; pp. 94-97.		3
Zucali,P.A.: Vinorelbine in pemetrexed-pretreated patients with malignant pleural mesothelioma. Lung Cancer Jun 2014; Vol 84, Issue 3; pp. 265-270.		3
Sorensen,J.B.: Cisplatin and vinorelbine first-line chemotherapy in non-resectable malignant pleural mesothelioma. British Journal of Cancer Jul 08, 2008; Vol 99, Issue 1; pp. 44-50		3

Zucali,PA, Ceresoli,GL, Garassino,I, et al: Gemcitabine and vinorelbine in pemetrexed-pretreated patients with malignant pleural mesothelioma. Cancer Apr 01, 2008; Vol 112, Issue 7; pp. 1555-1561.		3
Steele,J.P.: Phase II study of vinorelbine in patients with malignant pleural mesothelioma. Journal of Clinical Oncology Dec 01, 2000; Vol 18, Issue 23; pp. 3912-3917.		3
Fennell,D.A.: Phase II trial of vinorelbine and oxaliplatin as first-line therapy in malignant pleural mesothelioma. Lung Cancer Feb 2005; Vol 47, Issue 2; pp. 277-281.		3
Toyokawa,G., Takenoyama,M., Hirai,F., et al: Gemcitabine and vinorelbine as second-line or beyond treatment in patients with malignant pleural mesothelioma pretreated with platinum plus pemetrexed chemotherapy. Int J Clin Oncol Aug 2014; Vol 19, Issue 4; pp. 601-606.		3
Maruyama,R.: Triplet chemotherapy with cisplatin, gemcitabine and vinorelbine for malignant pleural mesothelioma. Japanese Journal of Clinical Oncology Aug 2005; Vol 35, Issue 8; pp. 433-438.		3

Stahel,R.A., Weder,W., Lievens,Y., et al: Malignant pleural mesothelioma: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Annals of Oncology May 2010; Vol 21, Issue SUPPL. 5; pp. v126-v128.		4
Chen,S.E. and Pace,M.B.: Malignant pleural mesotheliomaCHEN2012. Am J Health Syst Pharm Mar 01, 2012; Vol 69, Issue 5; pp. 377-385.		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
Margi Schiefelbein, PA	None	Edward Balaban, DO	None
Stacy LaClaire, PharmD	None	Thomas Marsland, MD	None
Felicia Gelsey, MS	None	James E. Liebmann, MD	None
		Jeffrey A. Bubis, DO	Other payments: Dendreon
		Keith Thompson, MD	None

ASSIGNMENT OF RATINGS:

*to meet requirement 4

	EFFICACY	STRENGTH OF RECOMMENDATION	COMMENTS	STRENGTH OF EVIDENCE
MICROMEDEX	---	---		B
Edward Balaban, DO	Ineffective	Class lll: Not Recommended	No real data to suggest effectiveness.	N/A
Thomas Marsland, MD	Evidence is Inconclusive	Class llb: Recommended, In Some Cases	There is only a single, old study that only suggests minimal to no benefit for Vinorelbine. Drug may help an occasional patient, but generally data do not support widespread use.	N/A

James E. Liebmann, MD	Evidence is Inconclusive	Class III: Not Recommended	Cisplatin and pemetrexed is currently the only standard regimen approved for treatment of mesothelioma. While there have been many Phase II trials of vinorelbine in this disease, all report limited activity. The trial for review only included chemotherapy arms that did not show improved survival compared to supportive care, though subset analysis of the vinorelbine arm suggested an improvement in survival with that drug. As the authors suggest, that result is hypothesis generating, but not evidence for efficacy. It is tempting to consider vinorelbine for patients not fit enough to receive cisplatin, but the current trial does not support that, since all patients in this trial were fit enough to receive cisplatin. Hence, at present there are no data to support the use of vinorelbine in place of cisplatin and pemetrexed in the treatment of mesothelioma.	N/A
Jeffrey A. Bubis, DO	Ineffective	Class III: Not Recommended	Vinorelbine has not been demonstrated to be an active agent in this clinical scenario.	N/A
Keith Thompson, MD	Ineffective	Class III: Not Recommended	None	N/A