

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 8/6/2018

PACKET: 1677

DRUG: Vinorelbine Tartrate

USE: Malignant mesothelioma of pleura

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)]

EVIDENCE CONSIDERED:

*to meet requirements 2 and 4

CITATION	STUDY-SPECIFIC COMMENTS	LITERATURE CODE
Kindler,H.L., Ismaila,N., Armato,S.G.,III, et al: Treatment of malignant pleural mesothelioma: American Society of Clinical Oncology Clinical Practice Guideline. J Clin Oncol Jan 18, 2018		S
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.		S
Zucali,P.A.: Vinorelbine in pemetrexed-pretreated patients with malignant pleural mesothelioma. Lung Cancer Jun 2014; Vol 84, Issue 3; pp. 265-270.		S
Zauderer,MG, Kass,SL, Woo,K, et al: Vinorelbine and gemcitabine as second- or third-line therapy for malignant pleural mesothelioma. Lung Cancer Jun 2014; Vol 84, Issue 3; pp. 271-274.		3

<p>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.</p>		<p>S</p>
<p>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.</p>		<p>S</p>
<p>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.</p>		<p>3</p>
<p>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.</p>		<p>3</p>
<p>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.</p>		<p>3</p>

<p>Baas,P., Fennell,D., Kerr,K.M., et al: Malignant pleural mesothelioma: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol Sep 01, 2015; Vol 26 Supplement 5, pp. v31-v39.</p>		<p>S</p>
<p>Scherpereel,A., Astoul,P., Baas,P., et al: Guidelines of the European Respiratory Society and the European Society of Thoracic Surgeons for the management of malignant pleural mesothelioma. European Respiratory Journal Mar 2010; Vol 35, Issue 3; pp. 479-495.</p>		<p>S</p>
<p>Ceresoli,G.L. and Zucali,P.A.: Vinca alkaloids in the therapeutic management of malignant pleural mesothelioma. Cancer Treat.Rev Dec 2015; Vol 41, Issue 10; pp. 853-858.</p>		<p>4</p>
<p>Addeo,A., Buffoni,L., and Di,Maio M.: Is there room for second-line treatment of pleural malignant mesothelioma?. JAMA Oncology Sep 01, 2017; Vol 3, Issue 9; pp. 1170-1171.</p>		<p>4</p>

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		
Stacy LaClaire, PharmD	None		
Catherine Sabatos, PharmD	None		
		John D Roberts	None
		Jeffrey Klein	None
		Richard LoCicero	Incyte Corporation Local PI for REVEAL. Study is a multicenter, non-interventional, non-randomized, prospective, observational study in an adult population for patients who have been diagnosed with clinically overt PV and are being followed in either community or academic medical centers in the US who will be enrolled over a 12-month period and observed for 36 months.

ASSIGNMENT OF RATINGS:

*to meet requirement 4

	EFFICACY	STRENGTH OF RECOMMENDATION	COMMENTS	STRENGTH OF EVIDENCE
MICROMEDEX	Evidence Favors Efficacy	Class IIb: Recommended, In Some Cases		B
John D Roberts	Ineffective	Class III: Not Recommended	The only randomized trial, albeit terminated early and underpowered, showed no benefit of vinorelbine over active supportive care. Non-randomized trials show modest response rates and mild toxicity that overall is not promising.	N/A
Jeffrey Klein	Evidence Favors Efficacy	Class IIb: Recommended, In Some Cases	For some patients the use of vinorelbine for Malignant mesothelioma of pleura showed in multiple studies some degree of effectiveness that some patients will benefit from. The adverse effect profile might limit or end its use in some patients however.	N/A



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Richard LoCicero	Evidence Favors Efficacy	Class IIb: Recommended, In Some Cases	Several studies have established clinical use of vinorelbine in the treatment of mesothelioma with acceptable toxicity.	N/A
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