TRUVEN HEALTH ANALYTICS

COMPENDIA TRANSPARENCY TRACKING FORM

DRUG: Thalidomide

INDICATION: Non-small cell lung cancer, advanced or metastatic, in combination with a platinum-based regimen

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, E, 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
Lee,S.M., Rudd,R., Woll,P.J., et al: Randomized double-blind placebo-controlled trial of thalidomide in combination with gemcitabine and Carboplatin in advanced non-small-cell lung cancer. J Clin Oncol Nov 01, 2009; Vol 27, Issue 31; pp. 5248-5254.	Study methodology comments: Key bias criteria evaluated were (1) random sequence generation of randomization; (2) lack of allocation concealment, (3) lack of blinding, (4) incomplete accounting of patients and outcome events, and (5) selective outcome reporting bias. The study was at low risk of bias for these key criteria, except for random sequence generation. The authors did not provide any information on this criterion so the risk of bias could not be determined.	S
Hoang,T., Dahlberg,S.E., Schiller,J.H., et al: Randomized phase III study of thoracic radiation in combination with paclitaxel and carboplatin with or without thalidomide in patients with stage III non-small-cell lung cancer: the ECOG 3598 study. J Clin Oncol Feb 20, 2012; Vol 30, Issue 6; pp. 616-622.	Study methodology comments: This was an open-label randomized trial. Overall, this study was at low risk for most of the key risk of bias criteria which included lack of blinding, incomplete accounting of patients and outcome events, and selective outcome reporting. The risk of bias associated with random sequence generation and allocation concealment was unclear and not discussed in the paper. It should be noted that in April 2007, at the third interim analysis of OS among eligible patients (73.9% information), the data monitoring committee recommended stopping the trial for futility because the 95% repeated CI for the OS HR was 0.81 to 1.34.	S
Jazieh,A.R., Komrokji,R., Gupta,A., et al: Phase II trial of thalidomide, irinotecan and gemcitabine in chemonaive patients with advanced non-small cell lung cancer. Cancer Invest Nov 2009; Vol 27, Issue 9; pp. 932-936.		3
Miller,A.A., Case,D., Atkins,J.N., et al: Phase II study of carboplatin, irinotecan, and thalidomide in patients with advanced non-small cell lung cancer. Journal of Thoracic Oncology: Official Publication of the International Association for the Study of Lung Cancer Oct 2006; Vol 1, Issue 8; pp. 832-836.		3

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Dudek,A.Z., Lesniewski-Kmak,K., Maddaus,M., et al: Phase II trial of neoadjuvant therapy with carboplatin, gemcitabine plus thalidomide for stage IIB and IIIA non-small cell lung cancer (NSCLC). Annals of Oncology 2007; Vol 18, pp. 184-184.		3
Flora,D.B., Kleykamp,B., Knapp,M., et al: A phase II trial of thalidomide (T), irinotecan (I) and gemcitabine (G) in chemonaive patients (pts) with advanced non-small cell lung cancer (NSCLC). Journal of Clinical Oncology Jul 15, 2004; Vol 22, Issue 14; pp. 680S-680S.		3
Seidler,C.W., Rooney,J., Kodali,D., et al: A phase I/II trial of docetaxel and daily thalidomide in patients with previously treated recurrent non-small cell lung cancer. Journal of Clinical Oncology Jul 15, 2004; Vol 22, Issue 14; pp. 686S-686S.		

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)

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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	Keith A. Thompson, MD	None
		Jeffrey A. Bubis, DO	Other payments; Dendreon
		Gerald J. Robbins, MD	None

ASSIGNMENT OF RATINGS:

*to meet requirement 4

	EFFICACY	STRENGTH OF RECOMMENDATION	COMMENTS	STRENGTH OF EVIDENCE
MICROMEDEX	---	---		B
Edward P. Balaban, DO	Ineffective	Class III - Not Recommended	Although the clinical studies have some inherent flaws, the addition of thalidomide to combination chemotherapy for non-small cell lung cancer has done little to improve treatment or outcome.	N/A
James E. Liebmann, MD	Ineffective	Class III - Not Recommended	The two large, well-conducted phase lll trials reviewed show no benefit from thalidomide in the treatment of stage lll or lV NSCLC. Instead, thalidomide caused toxicity. There is no justification for the use of thalidomide in non-small cell lung cancer.	N/A
Keith A. Thompson, MD	Ineffective	Class III - Not Recommended	None	N/A
Jeffrey A. Bubis, DO	Ineffective	Class III - Not Recommended	There is no data that supports an outcome benefit in this setting.	N/A

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Gerald J. Robbins, MD	Ineffective	Class III - Not Recommended	Although some bias may exist, it would be unlikely in these 2 large, randomized phase lll trials in both squamous and non-squamous histologies and 2 different chemotherapy protocol based trials.	N/A

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