TRUVEN HEALTH ANALYTICS

COMPENDIA TRANSPARENCY TRACKING FORM

DRUG: Docetaxel

INDICATION: Non-small cell lung cancer, advanced or metastatic, switch-therapy after gemcitabine/carboplatin

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, 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
Fidias,P.M., et al: Phase III study of immediate compared with delayed docetaxel after front-line therapy with gemcitabine plus carboplatin in advanced non-small-cell lung cancer. J Clin Oncol Feb 01, 2009; Vol 27, Issue 4; pp. 591-598.	Study methodology comments: Overall, this study has a crucial limitation for one criterion sufficient to lower ones confidence in the estimate effect. There was potentially high bias for lack of blinding since this was an open-label trial that did not use independent reviewers or assessors. There was low risk of bias for incomplete accounting of patients and outcome events, selective outcome reporting, and allocation concealment.	S
Hanna,N., et al: Phase III study of cisplatin, etoposide, and concurrent chest radiation with or without consolidation docetaxel in patients with inoperable stage III non-small-cell lung cancer: the Hoosier Oncology Group and U.S. Oncology. J Clin Oncol Dec 10, 2008; Vol 26, Issue 35; pp. 5755-5760.	Study methodology comments: Overall, this study was at low risk for all key criteria which included lack of blinding, incomplete accounting of patients and outcome events, and selective outcome reporting. Allocation concealment was unclear and not discussed in the paper. It is important to note that the trial was terminated early due to the preplanned interim analysis showing no benefit.	1
Jalal,S.I., et al: Updated survival and outcomes for older adults with inoperable stage III non-small-cell lung cancer treated with cisplatin, etoposide, and concurrent chest radiation with or without consolidation docetaxel: analysis of a phase III trial from the Hoosier Oncology Group (HOG) and US Oncology. Ann Oncol Dec 09, 2011; Vol 1, p. 1.	Study methodology comments: Literature analyst CB comments	1

Edelman,M.J., et al: Randomized phase II trial of sequential chemotherapy in advanced non-small cell lung cancer (SWOG 9806): carboplatin/gemcitabine followed by paclitaxel or cisplatin/vinorelbine followed by docetaxel. Clinical Cancer Research Aug 01, 2004; Vol 10, Issue 15; pp. 5022-5026.		1
Hillerdal,G., Randomized phase II study of gemcitabine and carboplatin +/- sequential docetaxel in non-small cell lung cancer. Lung Cancer Feb 2011; Vol 71, Issue 2; pp. 178-181.	Study methodology comments: Overall, this study had a crucial limitation for one criterion; there has high risk of bias for lack of blinding. The outcomes reported were vulnerable to bias from lack of blinding. There was low risk of bias for incomplete accounting of patients and outcome events, and selective outcome reporting. Allocation concealment was unclear and not discussed in the paper. It is important to note that this study was not powered for between-group comparisons on outcomes. The null hypothesis was that the GCD arm would be rejected if the median TTP among evaluable patients was less than 6 months. The actual TTP obtained was 4.7 months.	3
Binder,D., et al: Docetaxel/gemcitabine or cisplatin/gemcitabine followed by docetaxel in the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC): results of a multicentre randomized phase II trial. Cancer Chemother Pharmacol Jun 2007; Vol 60, Issue 1; pp. 143-150.		1
Ceribelli,A., et al: Sequential chemotherapy in nonsmall-cell lung cancer: cisplatin and gemcitabine followed by docetaxel. Cancer Feb 15, 2007; Vol 109, Issue 4; pp. 727-731.		3
Chiappori,A., et al: Phase II study of first-line sequential chemotherapy with gemcitabine-carboplatin followed by docetaxel in patients with advanced non-small cell lung cancer. Oncology 2005; Vol 68, Issue 4-6; pp. 382-390.		3

Clark,J.I., et al: Pilot study of sequential vinorelbine and cisplatin followed by docetaxel for selected IIIB and stage IV non-small cell lung cancer. Lung Cancer Nov 2001; Vol 34, Issue 2; pp. 271-277.		3
Azzoli,C.G., et al: American Society of Clinical Oncology Clinical Practice Guideline update on chemotherapy for stage IV non-small-cell lung cancer. J Clin Oncol Dec 20, 2009; Vol 27, Issue 36; pp. 6251-6266.		4
Azzoli,C.G., et al: 2011 Focused Update of 2009 American Society of Clinical Oncology Clinical Practice Guideline Update on Chemotherapy for Stage IV Non-Small-Cell Lung Cancer. J Clin Oncol Oct 01, 2011; Vol 29, Issue 28; pp. 3825-3831.		4
Coate,L.E. and Shepherd,F.A.: Maintenance therapy in advanced non-small cell lung cancer: Evolution, tolerability and outcomes. Therapeutic Advances in Medical Oncology 2011; Vol 3, Issue 3; pp. 139-157.		4
de,Marinis F., et al: Treatment of advanced non-small-cell lung cancer: Italian Association of Thoracic Oncology (AIOT) clinical practice guidelines. Lung Cancer Jul 2011; Vol 73, Issue 1; pp. 1-10.		4
Kim,Y.H. and Mishima,M.: Maintenance chemotherapy for non-small-cell lung cancer. Cancer Treatment Reviews Nov 2011; Vol 37, Issue 7; pp. 505-510.		4

Rossi,A., Torri,V., and Gridelli,C.: Switch maintenance versus second-line treatment in non-small cell lung cancer. Journal of Thoracic Oncology: Official Publication of the International Association for the Study of Lung Cancer Jul 2011; Vol 6, Issue 7; p. 1298.		4
Trigo Perez,J.M., Garrido,Lopez P., Felip,Font E., et al: SEOM clinical guidelines for the treatment of non-small-cell lung cancer: an updated edition. Clin Transl Oncol Nov 2010; Vol 12, Issue 11; pp. 735-741.		4
Varughese,S., Jahangir,K.S., Simpson,C.E., et al: A Paradigm Shift in the Treatment of Advanced Non-small Cell Lung Cancer. Am J Med Sci Feb 07, 2012; Vol E Pub, p. 1.		3
Zhang,X., Zang,J., Xu,J., et al: Maintenance therapy with continuous or switch strategy in advanced non-small cell lung cancer: a systematic review and meta-analysis. Chest Jul 2011; Vol 140, Issue 1; pp. 117-126.		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)

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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	Thomas McNeil Beck, MD	None
Felicia Gelsey, MS	None	Jeffrey A. Bubis, DO	Other payments: Dendreon
		James E. Liebmann, MD	None
		John M. Valgus, PharmD	None

ASSIGNMENT OF RATINGS:

*to meet requirement 4

	EFFICACY	STRENGTH OF RECOMMENDATION	COMMENTS	STRENGTH OF EVIDENCE
MICROMEDEX	---	---		B
Edward P. Balaban, DO	Evidence is inconclusive	Class IIb - Recommended, In Some Cases	ASCO's review is a fair summary. Switch TX to another cytoreductive agent may be helpful in a setting where a tumor is responding to original treatment – but that is based on fairly scant data. Therefore a "strength" of Class IIb at best and leans to a Class III (Not Recommended) category.	N/A
Thomas McNeil Beck, MD	Evidence is inconclusive	Class IIb - Recommended, In Some Cases	A small study without improvement in OS. Should consider comparison to no treatment receiving initial 4 cycles.	N/A
Jeffrey A. Bubis, DO	Ineffective	Class III - Not Recommended	No OS benefit. Increased toxicity relative to observation with no change in overall outcomes (except PFS) doesn't justify use.	N/A

James E. Liebmann, MD	Evidence favors efficacy	Class IIb - Recommended, In Some Cases	I agree with the current ASCO guidelines (Azzoli, et al, JCO, 29:3825) that state that Docetaxel is reasonable treatment for stage IV NSCLC that is at least stable after four cycles of platinum-based chemotherapy. I agree with the same guidelines that say that a break from chemotherapy is also reasonable. An argument could further be made that “switch-therapy” Docetaxel is best used in patients who had a response to initial platinum-based treatment.	N/A
John M. Valgus, PharmD	Evidence favors efficacy	Class IIa - Recommended, In Most Cases	Data in squam cell histology showing benefits in PFS but non-stat improvement in OS.	N/A