TRUVEN HEALTH ANALYTICS

COMPENDIA TRANSPARENCY TRACKING FORM

DRUG: Sunitinib malate

INDICATION: Non-small cell lung cancer, advanced or metastatic, in combination therapy, in previously treated patients

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
Scagliotti,G.V., et al: Sunitinib plus erlotinib versus placebo plus erlotinib in patients with previously treated advanced non-small-cell lung cancer: a phase III trial. Journal of Clinical Oncology Jun 10, 2012; Vol 30, Issue 17; pp. 2070-2078.	Study methodology comments: This was a phase 3, randomized, double-blind, placebo-controlled, multicenter, two-arm study. 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, and no additional biases were identified.	S
Socinski,M.A., Scappaticci,F.A., Samant,M., et al: Safety and efficacy of combining sunitinib with bevacizumab + paclitaxel/carboplatin in non-small cell lung cancer. Journal of Thoracic Oncology Mar 2010; Vol 5, Issue 3; pp. 354-360.		1
Gu,P., Wang,H.-M., Wang,W.-M., et al: Sunitinib in pretreated advanced non-small-cell lung carcinoma: A primary result from Asian population. Medical Oncology Jun 2011; Vol 28, Issue 2; pp. 578-583.		3
Novello,S., Camps,C., Grossi,F., et al: Phase II study of sunitinib in patients with non-small cell lung cancer and irradiated brain metastases. Journal of Thoracic Oncology Jul 2011; Vol 6, Issue 7; pp. 1260-1266.		3
Socinski,M.A., Novello,S., Brahmer,J.R., et al: Multicenter, phase II trial of sunitinib in previously treated, advanced non-small-cell lung cancer. Journal of Clinical Oncology 2008; Vol 26, Issue 4; pp. 650-656.		3

Novello,S., Scagliotti,G.V., Rosell,R., et al: Phase II study of continuous daily sunitinib dosing in patients with previously treated advanced non-small cell lung cancer. British Journal of Cancer 2009; Vol 101, Issue 9; pp. 1543-1548.		3
Ping,G., Hui-Min,W., Wei-Min,W., et al: Sunitinib in pretreated advanced non-small-cell lung carcinoma: a primary result from Asian population. Medical Oncology Jun 2011; Vol 28, Issue 2; pp. 578-583.		3

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
		Thomas McNeil Beck, MD	None
		Jeffrey A. Bubis, DO	Other payments: Dendreon

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 III - Not Recommended	Not much clinical data to draw on. Not much impact at all. Very little change in PFS (or ORR); toxicity greater. Doesn't appear to have a meaningful physiologic effect. Final rating – Class lll; Not Recommended.	N/A
James E. Liebmann, MD	Evidence is inconclusive	Class III - Not Recommended	The addition of Sunitinib to Erlotinib did not improve overall survival in patient with lung cancer. It added side effects compared to Erlotinib. The modest increases in response rate and progression free survival do not justify its use in this disease.	N/A
Keith A. Thompson, MD	Evidence favors efficacy	Class IIb - Recommended, In Some Cases	None	N/A
Thomas McNeil Beck, MD	Evidence is inconclusive	Class III - Not Recommended	No survival benefit observed- increased toxicity.	N/A
Jeffrey A. Bubis, DO	Evidence is inconclusive	Class IIb - Recommended, In Some Cases	No OS benefit. Minimal (though significant) PFS benefit.	N/A