TRUVEN HEALTH ANALYTICS™

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: **November 2015**

PACKET: **1242**

DRUG: **Vandetanib**

USE: Malignant tumor of ovary, recurrent, platinum-resistant

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, 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)]

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EVIDENCE CONSIDERED:

*to meet requirements 2 and 4

CITATION	STUDY-SPECIFIC COMMENTS	LITERATURE CODE
Coleman,R.L., et al: Randomised phase II study of docetaxel plus vandetanib versus docetaxel followed by vandetanib in patients with persistent or recurrent epithelial ovarian, fallopian tube or primary peritoneal carcinoma: SWOG S0904. European Journal of Cancer Jun 2014; Vol 50, Issue 9; pp. 1638-1648.	This was a randomized-controlled trial. Overall, this study has a crucial limitation for one criterion sufficient to lower ones confidence in the estimate effect. However, no statistically significant differences between groups on the outcomes were detected. There was potentially high risk of bias due to lack of blinding for subjective outcomes and low risk for the objective outcomes. There was low risk of bias for incomplete accounting of patients and outcome events, selective outcome reporting, and allocation concealment. The risk of bias associated with random sequence generation was unclear since the method of random sequence generation was not discussed.	S
Harter,P., et al: Addition of vandetanib to pegylated liposomal doxorubicin (PLD) in patients with recurrent ovarian cancer. A randomized phase I/II study of the AGO Study Group (AGO-OVAR 2.13). Invest.New Drugs Dec 2013; Vol 31, Issue 6; pp. 1499-1504.		3
Annunziata,C.M., et al: Vandetanib, designed to inhibit VEGFR2 and EGFR signaling, had no clinical activity as monotherapy for recurrent ovarian cancer and no detectable modulation of VEGFR2. Clinical Cancer Research Jan 15, 2010; Vol 16, Issue 2; pp. 664-672.		3

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Hilpert,F., et al: Vandetanib and Pegylated Liposomal Doxorubicin (PLD) in recurrent ovarian cancer: A phase I trail of the AGO Study Group. Journal of Cancer Research and Clinical Oncology Feb 2012; Vol 138 SUPPL. 1, p. 65.		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
Felicia Gelsey, MS	None	Edward Balaban, DO	None
Stacy LaClaire, PharmD	None	Jeffrey A. Bubis, DO	None
Catherine Sabatos, PharmD	None	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 III: Not Recommended	Very little data, but what data is posted demonstrated ineffectiveness.	N/A
Jeffrey A. Bubis, DO	Ineffective	Class III: Not Recommended	The addition of Vandetanib to Taxotere provided no significant benefit. This can be considered in patients who have exhausted all other options; but, in general, the data does not support its routine use.	N/A
Keith Thompson, MD	Evidence is Inconclusive	Class III: Not Recommended	None	N/A

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