TRUVEN HEALTH ANALYTICS™
an IBM Company

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 7/11/16

PACKET: 1203

DRUG: Everolimus

USE: Hodgkin's disease (clinical), Relapsed or refractory, in patients who had failed or were ineligible for autologous hematopoietic stem cell transplant or after failure of a gemcitabine-, vinorelbine-, or vinblastine containing 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, 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)]

TRUVEN HEALTH ANALYTICS™
an IBM Company

EVIDENCE CONSIDERED:

*to meet requirements 2 and 4

CITATION	STUDY-SPECIFIC COMMENTS	LITERATURE CODE
Johnston, PB et al. A Phase II Trial of The Oral Mtor Inhibitor Everolimus in Relapsed Hodgkin Lymphoma. Am J Hematol. 2010 May ; 85(5): 320–324.	Comments: This was an open-label, single-arm, phase II clinical trial. There was low risk of bias associated with selection of cohorts and assessment of outcomes. Data was gathered prospectively. All subjects were included in the analyses. The results should be interpreted with caution since the study lacked a control group.	S
Da Rocha, TS, et al. The Oral Mtor Inhibitor Everolimus in Relapsed and Refractory Hodgkin Lymphoma-Compassionate Use in 8 Centers in Brazil. December 3, 2015; Blood: 126 (23)	Abstract	S
Simon Rule. Everolimus in relapsed Hodgkin's lymphoma: Something exciting or a case of caveat mTOR? Am. J. Hematol. 85:313–314, 2010.		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)

CONTRIBUTORS:

*to meet requirement 3

PACKET PREPARATION	DISCLOSURES	EXPERT REVIEW	DISCLOSURES
Felicia Gelsey, MS	None		
Stacy LaClaire, PharmD	None		
Catherine Sabatos, PharmD	None		
		Jeffrey Klein	None
		John Roberts	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 is Inconclusive	Class IIb: Recommended, In Some Cases		B
Jeffrey Klein	Evidence is Inconclusive	Class IIb: Recommended, In Some Cases	The use of everolimus in Hodgkin's disease shows some efficacy though the studies were too small to draw a definitive conclusion. It also appears that using everolimus in combination with other agents shows a more favorable response then using it solo. The potential role of everolimus needs a more in depth evaluation. The mechanism of action of the product leads one to believe that this is the future direction in the treatment of Hodgkin's.	N/A

John Roberts	Evidence is Inconclusive	Class IIb: Recommended, In Some Cases	Two phase II reports in highly selected patient populations show promising response rates of modest duration with minimal bothersome toxicity in patients with heavily pretreated Hodgkin's Disease. As the first report is from 2010 and there appears to be only one subsequent report, the risk of publication bias, that is, the possibility that there have been multiple failed attempts to replicate this experience, is high.	N/A
Richard LoCicero	Evidence Favors Efficacy	Class IIb: Recommended, In Some Cases	Limited phase II data supports the use of everolimus in relapsed and refractory Hodgkin's disease, based on 42-47% response rates and acceptably low toxicity.	N/A