TRUVEN HEALTH ANALYTICS™
an IBM Company

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 11/8/16

PACKET: 1379

DRUG: Rituximab

USE: Burkitt's lymphoma (clinical) in combination with chemotherapy

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: R, S, C, L *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
Nie,M., Wang,Y., Bi,X.-W., et al: Effect of rituximab on adult Burkitt's lymphoma: a systematic review and meta-analysis. Annals of Hematology Jan 01, 2016; Vol 95, Issue 1; pp. 19-26.	Comments: This was a systematic review that included one randomized trial and five retrospective studies all comparing chemotherapy alone with chemotherapy plus rituximab. The Cochrane risk of bias tool and Newcastle-Ottawa scale were used to assess the quality of the included trials. The authors deemed the quality of the studies as generally moderate. This systematic review conducted a comprehensive literature search and provided information on eligibility criteria, study characteristics, and heterogeneity. The appropriate statistical tests were used.	S
Ribrag,V., Koscielny,S., Bosq,J., et al: Rituximab and dose-dense chemotherapy for adults with Burkitt's lymphoma: A randomised, controlled, open-label, phase 3 trial. The Lancet Jun 11, 2016; Vol 387, Issue 10036; pp. 2402-2411.	Comments: This was an open-label, randomized, phase 3 comparative trial of chemotherapy alone with chemotherapy plus rituximab. Overall, this study was at low risk of biases associated with poor random sequence generation, lack of blinding, incomplete accounting of patients and outcome events, and selective outcome reporting. The risk of bias associated with poor allocation concealment was unclear and not discussed in the paper.	S

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		
		John D Roberts	None
		Jeffrey Klein	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	Effective	Class I: Recommended		B
John D Roberts	Effective	Class I: Recommended	It seems likely that rituximab would enhance the efficacy of chemotherapy for Burkitt's Lymphoma on the basis of pharmacological principles and experiences with other B cell lymphoma. Now a single randomized trial, as well as several retrospective experiences, support this opinion.	N/A
Jeffrey Klein	Evidence Favors Efficacy	Class IIa: Recommended, In Most Cases	The addition of rituximab in combination with chemotherapy to treat burkitt's lymphoma appears to increase patient survival than not using it in one trial. Adverse effects were minimal though potential infusion reactions exist and must be taken into consideration.	N/A

Richard LoCicero	Effective	Class I: Recommended	The addition of Rituximab to standard chemotherapy for the treatment of Burkitt's lymphoma has been shown to be safe; and improve overall survival, progression free survival and remission rates.	N/A