TRUVEN HEALTH ANALYTICS

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: **MAY 2015**

PACKET: **1009**

DRUG: **Lenalidomide**

INDICATION: **Non-Hodgkin lymphoma, in combination with rituximab**

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, E, 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
Fowler,N.H., Davis,R.E., Rawal,S., et al: Safety and activity of lenalidomide and rituximab in untreated indolent lymphoma: An open-label, phase 2 trial. The Lancet Oncology Nov 2014; Vol 15, Issue 12; pp. 1311-1318.	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 for outcomes. All subjects were included in the analyses on overall survival. The results should be interpreted with caution since the study lacked a control group.	S
Wang,M., Fowler,N., Wagner-Bartak,N., et al: Oral lenalidomide with rituximab in relapsed or refractory diffuse large cell, follicular and transformed lymphoma: a phase II clinical trial. Leukemia Sep 2013; Vol 27, Issue 9; pp. 1902-1909	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 for outcomes. All subjects were included in the analyses. The results should be interpreted with caution since the study lacked a control group.	S
Tuscano,J.M., Dutia,M., Chee,K., et al: Lenalidomide plus rituximab can produce durable clinical responses in patients with relapsed or refractory, indolent non-Hodgkin lymphoma. British Journal of Haematology May 2014; Vol 165, Issue 3; pp. 375-381.	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 for outcomes.The results should be interpreted with caution since the study lacked a control group.	S

Zinzani PL, et al. Combination of Lenalidomide and Rituximab in Elderly Patients With Relapsed or Refractory Diffuse Large B-Cell Lymphoma: A Phase 2 Trial. Clinical Lymphoma, Myeloma & Leukemia, Vol. 11, No. 6, 462-6.	This was a prospective, single-arm, open-label, single-center, non-randomized phase II clinical trial. There was low risk of bias associated with selection of cohorts and assessment of outcomes. Data was gathered prospectively for outcomes. All patients were included in the analyses. The results should be interpreted with caution since the study lacked a control group.	S
Yamshon,S., Qi,L., Yu,C., et al: Correlative analysis and clinical update of a phase ii study using lenalidomide and rituximab in patients with indolent non-hodgkin lymphoma. Blood Oct 21, 2013; Vol 122, Issue 21. Date of Publication; p. 1.	This is an abstract.	4
Leonard,J., Gribben,J.G., Trneny,M., et al: AUGMENT: A phase 3, randomized trial to compare efficacy and safety of lenalidomide plus rituximab versus placebo plus rituximab in patients with relapsed/refractory indolent non-Hodgkin lymphoma (NHL). Journal of Clinical Oncology 2014; Vol 32, Issue 15 SUPPL. 1	This is an abstract.	4
Fowler,N.H., Neelapu,S.S., Hagemeister,F.B., et al: Lenalidomide and rituximab for untreated indolent lymphoma: Final results of a phase ii study. Blood Nov 16, 2012; Vol 120, Issue 21. Date of Publication; p. 1.	This is an abstract.	4

Dutia,M., DeRoock,I., Chee,K., et al: Analysis of a phase 2 study of lenalidomide and rituximab in relapsed or refractory non-Hodgkin's lymphoma. Haematologica Jun 2010; Vol 95 SUPPL. 2, p. 118.	This is an abstract.	4
Andorsky,D.J., Cataruozolo,P.E., Mouro,J.L., et al: MAGNIFY: A phase 3B, randomized trial of lenalidomide plus rituximab induction and maintenance therapy followed by lenalidomide single-agent versus rituximab maintenance in patients with relapsed/refractory indolent non-Hodgkin lymphoma (NHL). Journal of Clinical Oncology 2014; Vol 32, Issue 15 SUPPL. 1	This is an abstract.	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 Balaban, DO	None
Stacy LaClaire, PharmD	None	Jeffrey Patton, MD	None
Felicia Gelsey, MS	None	Jeffrey A. Bubis, DO	Other payments: Dendreon
		James E. Liebmann, MD	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	Evidence Favors Efficacy	Class IIb: Recommended, In Some Cases	Seems quite promising in phase II setting. Response rate approaches other salvage regimens. Will require further therapeutic trials to obtain a higher rating, but certainly looks promising.	N/A
Jeffrey Patton, MD	Evidence Favors Efficacy	Class IIb: Recommended, In Some Cases	None	N/A
Jeffrey A. Bubis, DO	Evidence Favors Efficacy	Class IIb: Recommended, In Some Cases	Non-randomized trials. This combination can be considered in patients with highly refractory disease for whom standard therapy has failed.	N/A

James E. Liebmann, MD	Evidence Favors Efficacy	Class IIb: Recommended, In Some Cases	The data presented in the trials for review show that the combination of lenalidomide and rituximab is active in B-cell lymphoma. However, no Phase III data exist comparing this combination with standard therapy, including treatment with rituximab alone. Therefore, this combination of drugs should be limited to patients with recurrent non-Hodgkin lymphoma, preferably in patients not candidates for more aggressive therapy (including transplant). Lenalidomide and rituximab should not be used as initial therapy of B-cell lymphomas.	N/A
Keith Thompson, MD	Evidence Favors Efficacy	Class IIb: Recommended, In Some Cases	None	N/A