IBM Watson Health

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: November 17, 2021

PACKET: 2143

DRUG: Oxaliplatin

USE: Mantle cell lymphoma; As combination therapy

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, 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)]

EVIDENCE CONSIDERED: *to meet requirements 2 and 4

CITATION	STUDY-SPECIFIC COMMENTS	LITERATURE CODE
Dreyling,M., Campo,E., Hermine,O., et al: Newly diagnosed and relapsed mantle cell lymphoma: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol Jul 01, 2017; Vol 28, Issue suppl 4; pp. iv62-iv71.		2
McKay, P, Leach, M, Jackson, B, et al: Guideline for the management of mantle cell lymphoma. Br J Haematol Jul 2018; Vol 182, Issue 1; pp. 46-62.		2
Le Gouill S, Thieblemont C, Oberic L, et al; LYSA Group. Rituximab after Autologous Stem-Cell Transplantation in Mantle-Cell Lymphoma. N Engl J Med. 2017 Sep 28;377(13):1250-1260.		1
Tessoulin, B, Chiron, D, Thieblemont, C, et al: Oxaliplatin before autologous transplantation in combination with high-dose cytarabine and rituximab provides longer disease control than cisplatin or carboplatin in patients with mantle-cell lymphoma: results from the LyMA prospective trial. Bone Marrow Transplant Jul 2021; Vol 56, Issue 7; pp. 1700-1709.	This was a post-hoc analysis of a randomized trial in patients with mantle-cell lymphoma. In this posthoc analysis, authors compared carboplatin, cisplatin, and oxaliplatin as induction therapy. The risk of potential bias associated with confounding, selection of participants, classification of interventions, and measurement and selection of outcome were deemed low risk. The risk of bias due to deviations from intended interventions was deemed high risk because investigators were free to switch interventions during induction. The risk of attrition bias was deemed high risk due to unequal switching rate in the treatment groups.	S
Obrador-Hevia, A, Serra-Sitjar, M, Rodriguez, J, et al: Efficacy of the GemOx-R regimen leads to the identification of Oxaliplatin as a highly effective drug against Mantle Cell Lymphoma. Br J Haematol Sep 2016; Vol 174, Issue 6; pp. 899-910.	This was a retrospective chart review that assessed the GemOx-R regimen in patients with mantle cell lymphoma. The risk of bias associated with confounding was deemed high risk. The risk of potential bias associated with selection of participants, classification and deviation from interventions, missing data, and measurement and selection of outcome were deemed low risk.	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
Megan Smith	None		
Stacy LaClaire, PharmD	None		
Catherine Sabatos, PharmD	None		
		John Roberts	None
		Todd Gersten	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
IBM MICROMEDEX	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases		B
Todd Gersten	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases	Oxaliplatin in combination has demonstrated robust efficacy prospectively prior to transplant, when compared to other platinum agent combinations, and retrospectively when combined with gemcitabine in up front or salvage setting.	
Richard LoCicero	Evidence is Inconclusive	Class III: Not Recommended	A retrospective chart reviewed identified cases of mantle cell lymphoma managed with oxaliplatin with favorable responses and without unexpected toxicities. A randomized trial evaluating the role of maintenance therapy after stem cell transplant in patients with mantle cell lymphoma also included an analysis of the efficacy of 3 different platinum derivatives (cisplatin, carboplatin and oxaliplatin). The analysis identified essentially comparable efficacy of the the 3 platinum derivatives used as the platinum in the DHAP regimen. No prospective randomized trial (presented) has evaluated the efficacy of oxaliplatin as first line therapy in this disease. While there is evidence of drug efficacy in this population, its role may be limited without further clinical trial evaluation.	

John Roberts	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases	In a retrospective analysis of a prospective randomized trial of combination induction chemotherapy with dexamethasone, cytarabine, rituximab and investigator's choice of cisplatin, carboplatin, or oxaliplatin, oxaliplatin was as effective and slightly less toxic than cisplatin or carboplatin. This conclusion is compromised, however, by the many features that might have introduced bias into trial conduct and analysis. A retrospective review of gemcitabine-oxaliplatin-rituximab showed that the combination is active and tolerable. Oxaliplatin is an acceptable platinum agent option; the best option is not known.	