IBM Watson Health

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: March 11, 2022

PACKET: 2179

DRUG: Ofatumumab

USE: Waldenström macroglobulinemia

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
Kastritis, E, Leblond, V, Dimopoulos, MA, et al: Correction to: Waldenstrom's macroglobulinaemia: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol May 01, 2019; Vol 30, Issue 5; pp. 860-862.		S
Furman, RR, Eradat, HA, DiRienzo, CG, et al: Once-weekly ofatumumab in untreated or relapsed Waldenström's macroglobulinaemia: an open-label, single-arm, phase 2 study. Lancet Haematol Jan 2017; Vol 4, Issue 1; pp. e24-e34.	This was a prospective, open-label, single-arm phase 2 clinical trial that investigated 2 different dosing schedules of ofatumumab in patients with Waldenström macroglobulinemia. The risk of bias due to confounding, selection, classification of intervention, measurement of outcome, selective reporting, and missing data were deemed low risk. The risk of bias associated with deviation from interventions was deemed moderate risk due to the authors amending the dosing partway through the trial. A major caveat of the study is the lack of a control group.	S
Gavriatopoulou, M, Kastritis, E, Kyrtsonis, M-C, et al: Phase 2 study of ofatumumab, fludarabine and cyclophosphamide in relapsed/refractory Waldenstrom's macroglobulinemia. Leuk Lymphoma Jun 2017; Vol 58, Issue 6; pp. 1506-1508.		3

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		
Patricia Shofi, RPh	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 III: Not Recommended	Ofatumumab has activity as would be expected based on knowledge of Rituximab data. The true efficacy cannot be assessed from this small single-arm study. Whether there is an efficacy advantage over Rituximab is unknown. My feeling is that single agent Ofatumumab adds little, beyond current therapeutics, to the current WM armamantarium.	
Richard LoCicero	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases	A single phase 2 single-arm study evaluated ofatumumab in the treatment of Waldenstrom's macroglobulinemia (treament naive and relapsed disease). Overall response rate was 52% without unexpected toxicity. While efficacy was demonstrated, other treatment regimens may be more effective. Ofatumumab may play a particular role in cases of rituximab-intolerant pattients; or those with high risk of IgM flare.	
John Roberts	Effective	Class IIb: Recommended, in Some Cases	In a single institution, single arm trial ofatumumab treatment of Waldenstrom's macroglobulinemia was well tolerated and resulted in a relatively high overall response rate of 59%. It seems likely that ofatumumab causes less myelosuppression than combinations that involve cytotoxic agents. The incidence of "IgM flare" was very low. There are many treatment options and inadequate information concerning their relative benefits and risks.	