IBM Watson Health

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 10/21/2019

PACKET: 1945

DRUG: Pomalidomide

USE: Multiple myeloma; Relapsed or refractory, in combination with a steroid in a triplet 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, L, 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
Richardson, PG, Oriol, A, Beksac, M, et al: Pomalidomide, bortezomib, and dexamethasone for patients with relapsed or refractory multiple myeloma previously treated with lenalidomide (OPTIMISMM): a randomised, open-label, phase 3 trial. Lancet Oncol Jun 2019; Vol 20, Issue 6; pp. 781-794.	This was an open-label, randomized Phase 3 trial that assessed bortezomib and dexamethasone with or without pomalidomide treatment for relapsed/refractory multiple myeloma. The risk of potential bias associated with randomization, attrition, and reporting were deemed low. The risk of potential bias associated with allocation concealment, performance, and detection were deemed high due to the open-label nature of the study. Another source of bias was identified as the study was funded by Celgene, marketer of Pomalyst (pomalidomide).	S
Baz,R.C., Martin,T.G.,III, Lin,H.Y., et al: Randomized multicenter phase 2 study of pomalidomide, cyclophosphamide, and dexamethasone in relapsed refractory myeloma. Blood May 26, 2016; Vol 127, Issue 21; pp. 2561-2568.	This was an open-label, randomized Phase 1/2 trial that assessed pomalidomide and dexamethasone with or without cyclophosphamide treatment for relapsed/refractory multiple myeloma. The risk of potential bias associated with randomization, attrition, and reporting were deemed low. The risk of potential bias associated with allocation concealment, performance, and detection were deemed high due to the open-label nature of the study. Another source of bias was identified as the study was funded by Celgene, marketer of Pomalyst (pomalidomide).	S
Shah, JJ, Stadtmauer, EA, Abonour, R, et al: Carfilzomib, pomalidomide, and dexamethasone for relapsed or refractory myeloma. Blood Nov 12, 2015; Vol 126, Issue 20; pp. 2284-2290.		2
Cohen, A, Spektor, TM, Stampleman, L, et al: Safety and efficacy of pomalidomide, dexamethasone and pegylated liposomal doxorubicin for patients with relapsed or refractory multiple myeloma. Br J Haematol Jan 2018; Vol 180, Issue 1; pp. 60-70.		2

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		
Margi Schiefelbein, PA	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
IBM MICROMEDEX	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases		B
Richard LoCicero	Effective	Class I: Recommended	Randomized clinical trials have established the efficacy of pomalidomide in triplet regimens in the treatment of relapsed/refractory multiple myeloma. No unexpected toxicity was observed.	
Jeffrey Klein	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases	The use of Pomalidomide in combination as a triplet regimen to treat multiple myeloma shows a very good progression free survival rate. Pomalidomide has a high degree of neutropenia and infection risk that was rather serious. These adverse reactions were viewed as serious by the authors of the clinical trials.	

John Roberts	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases	In patients with relapsed or refractory myeloma, including patients previously treated with lenalidomide, addition of pomalidomide and to dexamethasone and either bortezomib or cyclophosphamide resulted in increased response rates, modest improvements in progression free survival, and moderate increases in toxicity. No overall survival benefit was seen, although data were immature or potentially confounded by a cross-over study design. There are many treatment options in these patients, and clinical decision-making must be individualized based upon prior therapy, co-morbidity, potential toxicity, and goals of care.	