IBM Watson Health

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 6/11/2019

PACKET: 1902

DRUG: Ixazomib

USE: Multiple myeloma; Newly diagnosed, maintenance 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, L, R *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
Dimopoulos,M.A., Gay,F., Schjesvold,F., et al: Oral ixazomib maintenance following autologous stem cell transplantation (TOURMALINE-MM3): a double-blind, randomised, placebo-controlled phase 3 trial. Lancet Jan 19, 2019; Vol 393, Issue 10168; pp. 253-264.	This was a multi-center double-blind, placebo-controlled, randomized Phase III trial that assessed ixazomib maintenance therapy following autologous stem cell transplantation in patients with multiple myeloma. The risk of potential bias associated with randomization, allocation concealment, performance, detection, attrition, and reporting were deemed low. No other sources of bias were found.	S
Dimopoulos,M.A., Laubach,J.P., Echeveste Gutierrez,M.A., et al: Ixazomib maintenance therapy in newly diagnosed multiple myeloma: an integrated analysis of four phase I/II studies. Eur J Haematol 2019; Vol Epub, p. Epub.	This was a pooled analysis of four phase I/II trials that assessed ixazomib maintenance therapy in newly diagnosed multiple myeloma patients. There was low risk of bias associated with selection of cohort and assessment of outcome. Data was gathered prospectively for objective outcomes. No additional biases were found.	S
Kumar,S.K., Berdeja,J.G., Niesvizky,R., et al: Ixazomib, lenalidomide, and dexamethasone in patients with newly diagnosed multiple myeloma: long-term follow-up including ixazomib maintenance. Leukemia Jan 29, 2019; Vol Epub, p. Epub.		2
Vaxman,I. and Gertz,M.: Risk adapted post-transplant maintenance in multiple myeloma. Expert Rev Hematol 2019; Vol 12, Issue 2; pp. 107-118.		4

van de Donk,N.W.C.J. and Yong,K.: Oral proteasome inhibitor maintenance for multiple myeloma. Lancet Jan 19, 2019; Vol 393, Issue 10168; pp. 204-205.		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)

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 IIa: Recommended, in Most Cases		B
Jeffrey Klein	Evidence Favors Efficacy	Class IIa: Recommended, in Most Cases	The use of Ixazomib as maintenenace therapy in newly diagnosed multiple Myeloma patients appears to have some degree of benefit. The use was equally effective in transplant eligible and non-transplant eligible patients. However the high degree of grade 3 and higher adverse effects needs to be considered.	
Richard LoCicero	Evidence Favors Efficacy	Class IIa: Recommended, in Most Cases	A randomized phase III trials and data from four phase I/II trials have established the efficacy of ixazomib maintenance therapy after first line (newly diagnosed) therapy in the management of multiple myeloma. No unexpected toxicty was observed.	
John Roberts	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases	Ixazomib modestly prolongs disease free survival in patients with myeloma who have experienced a response to prior treatment. It is safe and generally well tolerated. It is unknown whether ixazomib prolongs overall survival.	