COMPENDIA TRANSPARENCY TRACKING FORM

DATE: May 16, 2023

OFF-LABEL ID #: 2537

DRUG NAME: Isatuximab-irfc

OFF-LABEL USE: Multiple myeloma; Newly diagnosed, transplant-eligible, in combination with lenalidomide, bortezomib, and dexamethasone

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 *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	LITERATURE CODE
Goldschmidt, H, Mai, EK, Bertsch, U, et al: Addition of isatuximab to lenalidomide, bortezomib, and dexamethasone as induction therapy for newly diagnosed, transplantation-eligible patients with multiple myeloma (GMMG-HD7): part 1 of an open-label, multicentre, randomised, active-controlled, phase 3 trial. Lancet Haematol Nov 2022; Vol 9, Issue 11; pp. e810-e821.	S
Leypoldt, LB, Besemer, B, Asemissen, AM, et al: Isatuximab, carfilzomib, lenalidomide, and dexamethasone (Isa-KRd) in front-line treatment of high-risk multiple myeloma: interim analysis of the GMMG-CONCEPT trial. Leukemia Mar 2022; Vol 36, Issue 3; pp. 885-888.	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		
Catherine Sabatos, PharmD	None		
		Todd Gersten	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 addition of Isatuximab to the RVD regimen for newly diagnosed multiple myeloma patients, demonstrated a reduction in residual disease. The rate of neutropenia and infection risk was higher in the Isatuximab group than the control group.	
Richard LoCicero	Effective	Class IIb: Recommended, in Some Cases	The addition of isatuximab to lenalidomide, bortezomib and dexamethasone improved the rate of minimal residual disease negativity compared to lenalidomide, bortezomib and dexamathssone alone in the first line treatment of transplant-eligible patient with multiple myeloma in an open-label, randomized phase III trial. No unexpected toxicity was observed. The isatuximab combination can be one of many options for treatment in this population.	
Todd Gersten	Evidence Favors Efficacy	Class IIa: Recommended, in Most Cases	Adding Isatuximab to the triplet of RVD boosted responses including MRD negativity rate in a single Phase III study. Whether this translates into an improvement in survivorship remains to be seen. The lack of a PFS/OS end point prevents a stronger Class I recommendation.	