COMPENDIA TRANSPARENCY TRACKING FORM

DATE: June 30, 2022

OFF-LABEL ID #: 2386

DRUG NAME: Polatuzumab Vedotin-piiq

OFF-LABEL USE: Diffuse non-Hodgkin's lymphoma, large cell (clinical); Intermediate- or high-risk, previously untreated, in combination with cyclophosphamide, DOXOrubicin, predniSONE, and rituximab

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, *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
Tilly, H, Morschhauser, F, Sehn, LH, et al: Polatuzumab Vedotin in Previously Untreated Diffuse Large B-Cell Lymphoma. N Engl J Med Jan 27, 2022; Vol 386, Issue 4; pp. 351-363.	This was a double-blind, active comparator, randomized Phase III clinical trial that compared a chemotherapy regimen containing polatuzumab (pola-R-CHP) to the R-CHOP regimen. The risk of potential bias associated with randomization, allocation concealment, performance, detection, attrition, and selective reporting were all deemed low risk. No other sources of bias were found.	S
Spinner, MA and Advani, RH: Current Frontline Treatment of Diffuse Large B-Cell Lymphoma. Oncology (Williston Park) Jan 20, 2022; Vol 36, Issue 1; pp. 51-58.		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	Effective	Class IIb: Recommended, in Some Cases		B
Todd Gersten	Effective	Class I: Recommended	The randomized trial demonstrates that the use of Polatuzumab with CHP-R is equivalent in 2-year survival to the longstanding standard-ofcare CHOP-R and should be therefore considered to a new additional standard of care option. The improvement in 2-year disease free survival versus CHOP-R solidifies it's place alongside, if not ahead of CHOP-R.	
Jeffrey Klein	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases	The addition of Polatuzumab to an existing regimen to treat diffuse nonhodgkin's lymphoma demonstrated an initial higher progression free survival, but a limited overall survival at the 2 year mark. The degree of adverse events was manageable.	

Richard LoCIcero	Effective	Class IIb: Recommended, in Some Cases	Polatuzumab (in combination with cyclophosphamide, doxorubicin, prednisone and rituximab) was compared to R-CHOP in a randomized phase III trial. 2-year progression-free survival was significantly improved with polatuzumab (76.6% vs. 70.2%) without unexpected or excess toxicity. Overall survival was not different between the two groups.	