COMPENDIA TRANSPARENCY TRACKING FORM

DATE: September 23, 2024

OFF-LABEL ID #: 2757

DRUG NAME: Blinatumomab

OFF-LABEL USE: B-cell acute lymphoblastic leukemia Precursor, in MRD-negative remission

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	LITERATURE CODE
Litzow MR, Sun Z, Mattison RJ, Paietta EM, Roberts KG, Zhang Y, Racevskis J, Lazarus HM, Rowe JM, Arber DA, Wieduwilt MJ, Liedtke M, Bergeron J, Wood BL, Zhao Y, Wu G, Chang TC, Zhang W, Pratz KW, Dinner SN, Frey N, Gore SD, Bhatnagar B, Atallah EL, Uy GL, Jeyakumar D, Lin TL, Willman CL, DeAngelo DJ, Patel SB, Elliott MA, Advani AS, Tzachanis D, Vachhani P, Bhave RR, Sharon E, Little RF, Erba HP, Stone RM, Luger SM, Mullighan CG, Tallman MS. Blinatumomab for MRD-Negative Acute Lymphoblastic Leukemia in Adults. N Engl J Med. 2024 Jul 25;391(4):320-333. doi: 10.1056/NEJMoa2312948. PMID: 39047240; PMCID: PMC11334054.	S
Gökbuget N, Boissel N, Chiaretti S, Dombret H, Doubek M, Fielding A, Foà R, Giebel S, Hoelzer D, Hunault M, Marks DI, Martinelli G, Ottmann O, Rijneveld A, Rousselot P, Ribera J, Bassan R. Management of ALL in adults: 2024 ELN recommendations from a European expert panel. Blood. 2024 May 9;143(19):1903-1930. doi: 10.1182/blood.2023023568. PMID: 38306595.	S

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
Stacy LaClaire, PharmD	None		
Catherine Sabatos, PharmD	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
MERATIVE MICROMEDEX	Effective	Class I: Recommended		B
Warren Brenner	Effective	Class I: Recommended	This large well conducted randomized trial showed blinatumomab to be a very effective agent in patients with precursor B ALL who despite being MRD negative still have a high risk of relapse. Given that relapse is often associated with a poor prognosis this study using a modern effective chemotherapy regimen showed a very significant benefit that was clinically significant and meaningful and establishes this agent as a standard of care in patients who would be eligible for this therapy. Although the increased neuropsychiatric toxicity is some concern the benefits clearly outweigh the risks and there is a significant survival advantage.	

Todd Gersten	Effective	Class I: Recommended	In a disease where relapses are notoriously difficult to treat, blinatumomab (when added to chemotherapy) improved overall survival vs chemotherapy alone when used to consolidate MRD negative first remissions.	
Jeffrey Klein	Effective	Class IIb: Recommended, in Some Cases	The use of Blintatumomab (in a chemotherapy regimen) in B-cell ALL MRD negative patients, demonstrated an improved overall survival, and relapse free survival when compared to a regimen that did not include Blinatumomab. The degree of grade 3 or 4 adverse effects, including “neuropsychiatric” with the Blinatumomab group most be considered.	