IBM Watson Health™

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: June 14, 2021

PACKET: 2110

DRUG: Nelarabine

USE: (PEDIATRIC) T-cell acute lymphoblastic leukemia; Newly diagnosed, intermediate- or high-risk disease, post-induction therapy in combination with the augmented Berlin-Frankfurt-Muenster (ABFM) 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, E, P *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
Dunsmore, KP, Winter, SS, Devidas, M, et al: Children's Oncology Group AALL0434: a phase III randomized clinical trial testing nelarabine in newly diagnosed T-cell acute lymphoblastic leukemia. J Clin Oncol Oct 01, 2020; Vol 38, Issue 28; pp. 3282-3293.	This was a multicenter, open-label, randomized Phase 3 trial that assessed post-induction nelarabine in young patients with newly diagnosed T-ALL. The risk of potential bias associated with randomization, allocation concealment, and detection were deemed low. The risk of performance bias was deemed high risk due to the open-label nature of the study. The risk of selective reporting bias was deemed high risk due to the primary outcome being DFS versus OS. The risk of attrition bias was deemed unclear risk due to lack of details concerning this information.	S
Hayashi, RJ, Winter, SS, Dunsmore, KP, et al: Successful outcomes of newly diagnosed T lymphoblastic lymphoma: results from Children's Oncology Group AALL0434. J Clin Oncol Sep 10, 2020; Vol 38, Issue 26; pp. 3062-3070.		1
Kadia, TM and Gandhi, V: Nelarabine in the treatment of pediatric and adult patients with T-cell acute lymphoblastic leukemia and lymphoma. Expert Rev Hematol Jan 2017; Vol 10, Issue 1; pp. 1-8.		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		
		John 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	Effective	Class I: Recommended		B
Jeffrey Klein	Evidence Favors Efficacy	Class IIa: Recommended, in Most Cases	The addition of Nelarabine to T cell ALL high risk and intermediate risk patients on the ABFM regimen, demonstrated a higher degree of disease free survival than those patients that did not receive nelarabine. In addition, those same patients had a greater CNS protection from their disease with nelarabine. The degree of adverse effects was minimal as well.	
Richard LoCicero	Effective	Class I: Recommended	In a phase III radomized trial conducted by the Children's Oncology Group, Nelarabine was shown to improve disease free survival when added to ABFM therapy in children and young adults with T-cell acute lymphoblastic leukemia. There was no unexpected toxicity.	
John Roberts	Effective	Class I: Recommended	In a randomized, open-label trial of standard risk-adjusted chemoradiotherapy regimens for the treatment of newly diagnosed, intermediate- or high-risk T-cell acute lymphoblastic leukemia in children and young adults nelarabine improved overall survival in all subgroups analyzed. It is recommended as a new standard of care.	