IBM Watson Health

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 1/3/2020

PACKET: 1962

DRUG: Inotuzumab ozogamicin

USE: Pre B-cell acute lymphoblastic leukemia; Relapsed or refractory (PEDIATRIC)

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, P, S *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
Kantarjian, H, Thomas, D, Jorgensen, J, et al: Inotuzumab ozogamicin, an anti-CD22-calecheamicin conjugate, for refractory and relapsed acute lymphocytic leukaemia: a phase 2 study. Lancet Oncol Apr 2012; Vol 13, Issue 4; pp. 403-411.		1
Bhojwani, D, Sposto, R, Shah, NN, et al: Inotuzumab ozogamicin in pediatric patients with relapsed/refractory acute lymphoblastic leukemia. Leukemia Apr 2019; Vol 33, Issue 4; pp. 884-892.	This was an international multi-site, retrospective cohort study that included all treated patients. There was low risk of bias associated with selection of cohorts and assessment of outcome. Data was gathered from de-identified medical records, and all subjects were included in the analyses. Follow-up time ranged from 19 to 736 days. A major caveat of the study was the absence of a control group.	S
Orellana-Noia, VM and Douvas, MG: Recent developments in adolescent and young adult (AYA) acute lymphoblastic leukemia. Curr Hematol Malig Rep Apr 2018; Vol 13, Issue 2; pp. 100-108.		4
Rytting, ME, Jabbour, EJ, O'Brien, SM, et al: Acute lymphoblastic leukemia in adolescents and young adults. Cancer Jul 01, 2017; Vol 123, Issue 13; pp. 2398-2403.		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		
Deanna Rossi, PharmD	None		
		Jeffrey Klein	None
		Adam Levy	None
		Lindsey Roke	None

ASSIGNMENT OF RATINGS:

*to meet requirement 4

	EFFICACY	STRENGTH OF RECOMMENDATION	COMMENTS	STRENGTH OF EVIDENCE
IBM MICROMEDEX	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases		B
Jeffrey Klein	Evidence Favors Efficacy	Class IIa: Recommended, in Most Cases	The use of Inotuzumab in ALL pediatric patients demonstrated a favorable response. Some children had complete remission. The medication was well tolerated with minimal adverse effects. The study however had a smll amount of participants.	
Adam Levy	Effective	Class IIb: Recommended, in Some Cases	As noted in the references attached, Inotuzumab ozogamicin (InO) has demonstrated efficacy in pediatric patients with relapsed/refractory pre B-cell ALL. Also noted in the most comprehensive review of Inotuzumab ozogamicin in children, “There are currently two prospective pediatric phase II trials of InO for patients with relapsed/refractory, one in the United States (NCT02981628) and one in Europe (EudraCT 2016–000227–71); the latter is planned in combination with chemotherapy after the single agent phase. Data generated from these studies will provide more comprehensive data on the efficacy and toxicities of InO as it is potentially moved to frontline therapy.” (Bhojwani et al) As such, it is most appropriate to conclude that InO is recommended in some cases (Class IIb) until further evidence demostrates it should be used more broadly.	

Lindsey Roke	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases	I believe Inotuzumab has a lot of potential to be salvage therapy in relapsed/refractory B-ALL for pediatric patients. It is relatively safe and the side effects seen in the provided study are similar to those seen in adult studies. The response rate with complete remission was impressive at 67%, however, with only 1 small retrospective study, I'm not sure I can rate my recommendation any higher. Once larger prospective trials are completed, I believe this recommendation could be increased.	