COMPENDIA TRANSPARENCY TRACKING FORM

DATE: April 17, 2026

OFF-LABEL ID #: MDXOLS-418

DRUG NAME: Inotuzumab ozogamicin

OFF-LABEL USE: Precursor B-cell acute lymphoblastic leukemia, Newly diagnosed, CD22 positive, as induction therapy in patients unable to receive intensive chemotherapy

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, 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	LITERATURE CODE
Wieduwilt MJ, Yin J, Kour O, et al. Inotuzumab Ozogamicin Then Blinatumomab for Older Adults With Newly Diagnosed B-Cell ALL: Alliance Study A041703 Cohort 1 Results. J Clin Oncol. 2025;43(32):3526-3535. PMID: 41026957.	S
Chevallier P, Leguay T, Delord M, et al. Inotuzumab Ozogamicin and Low-Intensity Chemotherapy in Older Patients With Newly Diagnosed CD22^{+} Philadelphia Chromosome-Negative B-Cell Precursor Acute Lymphoblastic Leukemia. J Clin Oncol. 2024;42(36):4327-4341. PMID: 39418626.	S
Stelljes M, Raffel S, Alakel N, et al. Inotuzumab Ozogamicin as Induction Therapy for Patients Older Than 55 Years With Philadelphia Chromosome-Negative B-Precursor ALL. J Clin Oncol. 2024;42(3):273-282. PMID: 37883727.	S
Jabbour E, Short NJ, Senapati J, et al. Mini-hyper-CVD plus inotuzumab ozogamicin, with or without blinatumomab, in the subgroup of older patients with newly diagnosed Philadelphia chromosome-negative B-cell acute lymphocytic leukaemia: long-term results of an open-label phase 2 trial. Lancet Haematol. 2023;10(6):e433-e444. PMID: 37187201	3
Kantarjian H, Ravandi F, Short NJ, et al. Inotuzumab ozogamicin in combination with low-intensity chemotherapy for older patients with Philadelphia chromosome-negative acute lymphoblastic leukaemia: a single-arm, phase 2 study. Lancet Oncol. 2018;19(2):240-248. PMID: 29352703.	3
Kantarjian H, Short NJ, Jain N, et al. Hyper-CVAD and Sequential Blinatumomab Without and With Inotuzumab in Young Adults With Newly Diagnosed Philadelphia Chromosome-Negative B-Cell Acute Lymphoblastic Leukemia. *Am J Hematol*. 2025;100(3):402-407. PMID: 39757533.	1
Gökbuget N, Boissel N, Chiaretti S, et al. Management of ALL in adults: 2024 ELN recommendations from a European expert panel. Blood. 2024;143(19):1903-1930. PMID: 38306595.	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
Stacy LaClaire, PharmD	None		
Catherine Sabatos, PharmD	None		

ASSIGNMENT OF RATINGS:

*to meet requirement 4

	EFFICACY	STRENGTH OF RECOMMENDATION	COMMENTS	STRENGTH OF EVIDENCE
MERATIVE MICROMEDEX	Effective	Class IIa: Recommended, in Most Cases		
Jeffrey Klein	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases	The use of Inotuzumab to treat newly diagnosed ALL patients demonstrated a significant 1 year overall survival rate. These patients had the following characteristics: CD 22+, Ph-, and B-cell precursor. The adverse effect profile was favorable as well.	
Todd Gersten	Effective	Class I: Recommended	Across several trials, as monotherapy or in combination with other agents, Inotuzumab has shown clinically significant efficacy in the submitted patient population..	

Warren Brenner	Effective	Class IIa: Recommended, in Most Cases	These different single arm but multicenter trials showed that the use of Inotuzumab in patients with a difficult to treat leukemia were effective in various combinations including as a single agent, with steroids and with low dose chemotherapy. These were all in an older patient population where effective treatment is shown to have significant toxicity and generally poor outcomes in Philadelphia chromosome negative ALL. I rated the treatment as effective as there were high rates of complete remission and favorable EFS and OS. Strength of recommendation is class IIa as these were single arm studies with different treatments and schedules with no comparator arm accounting for a class IIa recommendation. Its general effectiveness and acceptable toxicity profile warrant its recommendation in patients similar to the ones enrolled in these 3 different studies. However, the single arm and complexities of 3 different treatment backbones led to class IIa rather than class I recommendation submitted patient population	