COMPENDIA TRANSPARENCY TRACKING FORM

DATE: August 22, 2023

OFF-LABEL ID #: 2572

DRUG NAME: Temozolomide

OFF-LABEL USE: (Pediatric) Medulloblastoma; Relapsed or recurrent

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, 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)]

© 2023 Merative

EVIDENCE CONSIDERED:

*to meet requirements 2 and 4

CITATION	LITERATURE CODE
Ghilardi, G, Chong, EA, Svoboda, J, et al: Bendamustine is safe and effective for lymphodepletion before tisagenlecleucel in patients with refractory or relapsed large B-cell lymphomas. Ann Oncol Sep 2022; Vol 33, Issue 9; pp. 916-928.	S
Amini, L., Silbert, S.K., Maude, S.L. *et al.* Preparing for CAR T cell therapy: patient selection, bridging therapies and lymphodepletion. *Nat Rev Clin Oncol* **19**, 342–355 (2022).	4
Bechman N, Maher J. Lymphodepletion strategies to potentiate adoptive T-cell immunotherapy - what are we doing; where are we going? Expert Opin Biol Ther. 2021 May;21(5):627-637. Epub 2020 Dec 28. PMID: 33243003.	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)

© 2023 Merative

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	Evidence Favors Efficacy	Class IIa: Recommended, in Most Cases		B
Rachel Offenbacher	Evidence Favors Efficacy	Class IIa: Recommended, in Most Cases	Temozolamide has been shown to be effective as both monotherapy as well as in combination with Irinotecan and Avastin and with Topotecan for relapsed or recurrent medulloblastoma with an overall improved median survival. It can be administered safely without toxicity. Although there was evidence of morbidity associated with the treatment such as F&N, there was no change in overall life threatening correlations due to Temozolamide. Of note, efficacy was demonstrated in all patients who has been heavily pretreated.	

© 2023 Merative

Richard LoCicero	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases	Clinical trials have established efficacy of temozolomide in the treatment of relapsed/recurrent pediatric medulloblastoma. A phase II trial of 40 patients demonstrated a 42.5% response rate. Additionally, two phase II trials have evaluated temozolomide in combination with irinotecan demonstrating reponse rates of ~30%. Phase III trials are not available.	
Jeffrey Klein	Evidence Favors Efficacy	Class IIa: Recommended, in Most Cases	The use of Temozolamide for pediatric medulloblastoma patients who have relapsed is quite effective. It is not very clear if temozolamide can be used as monotherapy. The adverse effect profile is very tolerable. The studies for this evaluation are small, and the most effective dose needs to be determined.	

© 2023 Merative