IBM Watson Health

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: August 23, 2021

PACKET: 2120

DRUG: Vedolizumab

USE: Acute graft-versus-host disease - Steroid-refractory

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, 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
Penack, O, Marchetti, M, Ruutu, T, et al: Prophylaxis and management of graft versus host disease after stem-cell transplantation for haematological malignancies: updated consensus recommendations of the European Society for Blood and Marrow Transplantation. Lancet Haematol Feb 2020; Vol 7, Issue 2; pp. e157-e167.		S
Floisand, Y, Schroeder, MA, Chevallier, P, et al: A phase 2a randomized clinical trial of intravenous vedolizumab for the treatment of steroid-refractory intestinal acute graft-versus-host disease. Bone Marrow Transplant Jun 09, 2021; Vol Epub, p. Epub.	This was an open-label phase 2a randomized trial that assessed two different doses of vedolizumab in patients with acute gastrointestinal graft versus host disease. The risk of potential bias associated with randomization, allocation concealment, performance, attrition, and selective reporting were deemed low risk. The risk of bias associated with detection was deemed high risk due to the use of investigator-assessed response as primary outcome without blinding.	S
Floisand, Y, Lazarevic, VL, Maertens, J, et al: Safety and Effectiveness of Vedolizumab in Patients with Steroid-Refractory Gastrointestinal Acute Graft-versus-Host Disease: A Retrospective Record Review. Biol Blood Marrow Transplant Apr 2019; Vol 25, Issue 4; pp. 720-727.		3
Danylesko, I, Bukauskas, A, Paulson, M, et al: Anti-Alpha4Beta7 integrin monoclonal antibody (vedolizumab) for the treatment of steroid-resistant severe intestinal acute graft-versus-host disease. Bone Marrow Transplant Jul 2019; Vol 54, Issue 7; pp. 987-993.		3

Mehta, RS, Saliba, RM, Jan, A, et al: Vedolizumab for Steroid Refractory Lower Gastrointestinal Tract Graft-Versus-Host Disease. Transplant Cell Ther Mar 2021; Vol 27, Issue 3; pp. 272.e1-272.e5.	This was a retrospective review of medical charts that assessed vedolizumab in patients with acute gastrointestinal graft versus host disease. The risk of potential bias associated with confounding, selection of participants, classification and deviation from interventions, missing data, measurement of outcome, and selective reporting were deemed low risk.	S
Coltoff, A, Lancman, G, Kim, S, et al: Vedolizumab for treatment of steroid-refractory lower gastrointestinal acute graft-versus-host disease. Bone Marrow Transplant Jul 2018; Vol 53, Issue 7; pp. 900-904.		4
Floisand, Y, Lundin, KE, Lazarevic, V, et al: Targeting Integrin alpha4beta7 in Steroid-Refractory Intestinal Graft-versus-Host Disease. Biol Blood Marrow Transplant Jan 2017; Vol 23, Issue 1; pp. 172-175.		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
		Todd Gersten	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	Evidence is Inconclusive	Class III: Not Recommended		B
Todd Gersten	Ineffective	Class III: Not Recommended	Vedolizumab has not demonstrated clinically significant efficacy in steroid- refractory intestinal aGVHD.	
Richard LoCicero	Evidence is Inconclusive	Class III: Not Recommended	The use of vedolizumab for the treatment of steroid-refractory acute graft-versus-host disease is not currently supported by clinical trial outcomes.	
John Roberts	Evidence is Inconclusive	Class III: Not Recommended	Transient responses to vedolizumab in the treatment of steroid-refractory acute graft-versus-host disease, especially in patients with gastrointestinal involvement, but their duration generally is short and death rates remained high. No significant toxicities were attributed to vedolizumab. Of some concern, survival was lower in patients receiving the higher of 2 doses in a small randomized trial that was terminated early due to lack of efficacy. None of these reported experiences benefited from confirmation of response by evaluators unaware of the treatment received. Vedolizumab may have a role that might be discussed by future investigations, but it is recommended for use outside of a clinical trial at this time.	