IBM Watson Health

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 3/25/2021

PACKET: 1878

DRUG: Brentuximab vedotin

USE: Hodgkin's disease (clinical); 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, E, R *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
O'Connor, OA, Lue, JK, Sawas, A, et al: Brentuximab vedotin plus bendamustine in relapsed or refractory Hodgkin's lymphoma: an international, multicentre, single-arm, phase 1-2 trial. Lancet Oncol Feb 2018; Vol 19, Issue 2; pp. 257-266.		1
Cole, PD, McCarten, KM, Pei, Q, et al: Brentuximab vedotin with gemcitabine for paediatric and young adult patients with relapsed or refractory Hodgkin's lymphoma (AHOD1221): a Children's Oncology Group, multicentre single-arm, phase 1-2 trial. Lancet Oncol Sep 2018; Vol 19, Issue 9; pp. 1229-1238.	This was an open-label, phase 1-2 study that investigated treatment with brentuximab vedotin in combination with gemcitabine in North American children and young adults with relapsed, refractory, or advanced Hodgkin's lymphoma. The risk of bias associated with unmeasured confounders, selection, classification and deviation from intervention, missing data, and measurement of outcome were deemed low risk. Reporting bias was deemed high risk because the primary outcome was reponse-related rather than survival-related.	S
Locatelli, F, Mauz-Koerholz, C, Neville, K, et al: Brentuximab vedotin for paediatric relapsed or refractory Hodgkin's lymphoma and anaplastic large-cell lymphoma: a multicentre, open-label, phase 1/2 study. Lancet Haematol Oct 2018; Vol 5, Issue 10; pp. e450-e461.	This was an open-label, international, phase 1-2 study that investigated treatment with brentuximab vedotin in children with CD30+, relapsed or refractory Hodgkin's lymphoma. The risk of bias associated with unmeasured confounders, selection, classification and deviation from intervention, missing data, and measurement of outcome were deemed low risk. Reporting bias was deemed high risk because the primary outcome was reponse-related rather than survival-related.	S

Koga, Y, Sekimizu, M, Iguchi, A, et al: Phase I study of brentuximab vedotin (SGN-35) in Japanese children with relapsed or refractory CD30-positive Hodgkin's lymphoma or systemic anaplastic large cell lymphoma. Int J Hematol May 2020; Vol 111, Issue 5; pp. 711-718.		3

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		
		Adam Levy	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 IIa: Recommended, in Most Cases		B
Adam Levy	Effective	Class IIa: Recommended, in Most Cases	As demonstrated by Locatelli et al, there is single agent tolerability and efficacy of brentuximab vedotin in pediatric patients with refractory or recurrent Hodgkin lymphoma. Importantly, however, as noted by Cole et al., "Brentuximab vedotin is increasingly being incorporated into initial therapy...Although some patients with relapsed Hodgkin lymphoma will respond to Brentuximab vedotin more than once, it is possible that the Brentuximab complete response rate will be lower among ...patients who relapse after prior Brentuximab vedotin therapy than what was observed in this study of Brentuximab naive patients. An additional limitation is that this Phase 1/2 study was not designed as a randomized trial, prohibiting any direct comparison of results after this combination with other recently published salvage regimens." As such, there is ample support for brentuximab vedotin for relapsed or refractory pediatric patients with Hodgkin lymphoma in most cases, but there may be other salvage and second line therapies equally or more appropriate for specific patients based on their prior therapies or toxicities from prior treatments.	
Jeffrey Klein	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases	The use of Brentuximab to treat pediatric Hodgkin's disease in relapsed or refractory patients appears to have a decent overall response with minimal adverse effects. However the study was small. It also seems that more studies are needed to determine the true effectiveness of this product. More information is needed to see if brentuximab has better efficacy as a first line agent.	
Richard LoCicero	Effective	Class I: Recommended	Two clinical trials have established the efficacy of Brentuximab for the treatment of relapsed/refractory Hodgkin's disease in pediatric patients. No unexpected toxicity was observed.	