IBM Watson Health

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: December 1, 2021

PACKET: 2149

DRUG: Ibrutinib

USE: Hairy cell leukemia (clinical); Relapsed/Refractory, monotherapy

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	STUDY-SPECIFIC COMMENTS	LITERATURE CODE
Parry-Jones, N, Joshi, A, Forconi, F, et al: Guideline for diagnosis and management of hairy cell leukaemia (HCL) and hairy cell variant (HCL-V). Br J Haematol Dec 2020; Vol 191, Issue 5; pp. 730-737.		S
Rogers, KA, Andritsos, LA, Wei, L, et al: Phase 2 study of ibrutinib in classic and variant hairy cell leukemia. Blood Jun 24, 2021; Vol 137, Issue 25; pp. 3473-3483.	This was a prospective single-arm phase II trial that assessed ibrutinib in patients with refractory hairy cell leukemia. The risk of potential bias associated with confounding, selection of participants, classification and deivation from interventions, missing data, measurement and selection of outcome were all deemed low.	S

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	Effective	Class IIb: Recommended, in Some Cases		B
Todd Gersten	Effective	Class I: Recommended	In relapsed, refractory HCL there are few therapeutic options. The very limited data available demonstrate the effectiveness of Ibrutinib.	
Richard LoCicero	Evidence is Inconclusive	Class IIb: Recommended, in Some Cases	Clinical trial date for the use of ibrutinib in the treatment of relapse/refractory hairy cell leukemia is limited. A single phase II trial evaluated ibrutinib in 37 patients. Response rate was 54% and there was no unexpected toxicity. The use of ibrutinib may be limited to progressive disease after exhausting other treatment options in this rare disease.	
John Roberts	Effective	Class IIb: Recommended, in Some Cases	In a single arm study ibrutinib showed activity, total response rate ~ 50%, and modest toxicity against Hairy cell leukemia in 37 predominantly heavily pretreated patients. Ibrutinib is one of several treatment options for relapsed/refractory disease.	