IBM Watson Health

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 2/18/2020

PACKET: 1949

DRUG: Edoxaban

USE: Thromboembolism of vein, Following parenteral therapy; Malignant neoplastic disease

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: A, 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
Kahale LA, Hakoum MB, Tsolakian IG, et al. Anticoagulation for the long-term treatment of venous thromboembolism in people with cancer. Cochrane Database of Systematic Reviews 2018, Issue 6. Art. No.: CD00665		1
Li A, Garcia DA, Lyman GH, et al. Direct oral anticoagulant (DOAC) versus low-molecular-weight heparin (LMWH) for treatment of cancer associated thrombosis (CAT): A systematic review and meta-analysis. Thrombosis Research 173 (2019) 158–163.		1
Raskob GE, van Es N, Verhamme P, et al. Edoxaban for the Treatment of Cancer-Associated Venous Thromboembolism. N Engl J Med 2018;378:615-24.	This was an open-label, randomized-controlled trial that assessed edoxaban versus dalteparin for the treatment of venous thromboembolism in patients with cancer. The risk of potential bias associated with randomization, allocation concealment, detection, attrition, and reporting were deemed low. The risk of potential bias associated with performance was deemed high due to the open-label nature of the trial, although the authors used an independent clinical events committee to adjudicate major bleeding outcomes. Additional bias could stem from the study being funded by Daiichi Sankyo.	S
Raskob GE, Ageno W, Cohen AT, et al. Extended duration of anticoagulation with edoxaban in patients with venous thromboembolism: a post-hoc analysis of the Hokusai-VTE study. Lancet Haematol 2016; 3: e228–36.		1

Raskob GE, van Es N, Segers A, et al. Edoxaban for venous thromboembolism in patients with cancer: results from a non-inferiority subgroup analysis of the Hokusai-VTE randomised, double-blind, double-dummy trial Lancet Haematol 2016; 3: e379–87	This was a pre-specified non-inferiority subgroup analysis of the Hokusai-VTE study. Hokusai-VTE was a multicentre double-blind, double-dummy randomized clinical trial that assessed edoxaban versus warfarin for venous thromboembolism; this analysis focused on the subgroup of patients with cancer-associated VTE. There was low risk of bias associated with selection and comparability of cohorts, and assessment of outcomes. Data was gathered prospectively for objective outcomes in a controlled clinical trial environment. Additional bias could stem from the study being funded by Daiichi Sankyo.	S
Farge D, Debourdeau P, Beckers M, et al. International clinical practice guidelines for the treatment and prophylaxis of venous thromboembolism in patients with cancer. J Thromb Haemost. 2013;11(1):56–70.		2
Key NS, Khorana AA, Kuderer NM, et al. Venous Thromboembolism Prophylaxis and Treatment in Patients With Cancer: ASCO Clinical Practice Guideline Update. Journal of Clinical Oncology 0 0:0.		S
Khorana AA, Noble S, Lee AYY, et al. Role of direct oral anticoagulants in the treatment of cancer-associated venous thromboembolism: guidance from the SSC of the ISTH. Journal of Thrombosis and Haemostasis, 16: 1891–1894.		2

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		
Margi Schiefelbein, PA	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
IBM MICROMEDEX	Effective	Class IIb: Recommended, in Some Cases		B
Jeffrey Klein	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases	The use of Edoxaban to treat or prevent thromboembolism in cancer patients shows a degree of effectiveness when compared to warfarin. Edoxaban was equally effective with dalteparin but showed a higher risk of major bleeding.	
John Roberts	Effective	Class IIb: Recommended, in Some Cases	In patients living with cancer who had recently experienced a venous thromboembolism, recurrent thromboemblism events and bleeding were similarly common in patients treated with edoxaban or warfarin and in patients treated wtih edoxaban or dalteparin. Edoxaban is an option for the secondary prevention of venous thromboembolism.	
Richard LoCicero	Effective	Class I: Recommended	Edoxaban has been shown to be non-inferior to other standard therapies for management of DVT in patient with cancer.	