IBM Watson Health

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 2/20/2020

PACKET: 1952

DRUG: Rivaroxaban

USE: Thromboembolism of vein, Prophylaxis; In high-risk outpatients, 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
Li A, Kuderer NM, Garcia DA, et al. Direct oral anticoagulant for the prevention of thrombosis in ambulatory patients with cancer: A systematic review and meta-analysis. J Thromb Haemost. 2019; 17:2141–2151.		1
Khorana AA, Soff GA, Kakkar AK, et al. Rivaroxaban for Thromboprophylaxis in High-Risk Ambulatory Patients with Cancer. N Engl J Med 2019; 380:720-8.	This was a multicenter double-blind, placebo-controlled, randomized Phase 3b trial. The risk of potential bias associated with randomization, performance, detection, attrition, and reporting were deemed low. The risk of potential bias that could result from not rigorously implementing allocation concealment was unclear due to the lack of information on these methods. No other sources of bias were found.	S
Wang TF, Zwicker JI, Ay C, et al. The use of direct oral anticoagulants for primary thromboprophylaxis in ambulatory cancer patients: Guidance from the SSC of the ISTH. J Thromb Haemost. 2019; 17:1772–1778.		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

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	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases		B
Jeffrey Klein	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases	The use of Rivaroxaban to prevent deep vein thrombosis in high risk oncology patients demonstrated better effeicacy than placebo. However the risk of major bleeds was higher and must be considered prior to commencing therapy.	
John Roberts	Ineffective	Class III: Not Recommended	In a single placebo controlled trial, rivaroxaban did not significantly reduce the frequency of venous thromboembolism over 180 days in patients living with cancer and at greater than average risk. A substantial minority of patients stopped study treatment, both rivaroxaban and placebo, early. A pre-planned analysis did show a significant reduction in venous thromboembolism when data were analyzed for the time periods when patients were on study intervention. This suggests that rivaroxaban might be effective if factors leading to treatment discontinuation could be identified and addressed. Although it might be tempting to recommend prophylactic rivaroxaban to patients at high or very high risk, an exploratory analysis did not suggest that this strategy would be effective.	
Richard LoCicero	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases	Rivaroxaban is associated with a lower risk of venous thromboembolism in patient receiving chemotherapy.	