



COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 2/20/2020

PACKET: 1950

DRUG: Apixaban

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.		2
Carrier M, Abou-Nassar K, Mallick R, et al. Apixaban to Prevent Venous Thromboembolism in Patients with Cancer. N Engl J Med 2019; 380:711-9.	This was a double-blind, placebo-controlled, randomized clinical trial that assessed apixaban for the prevention of venous thromboembolism in patients with cancer. The risk of potential bias associated with randomization, allocation concealment, performance, detection, attrition, and reporting were all deemed low. No other sources of bias were found.	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



<p>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.</p>		<p>S</p>
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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	<p>Incyte Corporation</p> <p>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.</p>



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 IIa: Recommended, in Most Cases	The use of Apixaban to prevent deep vein thromboembolism is effective in high risk oncology patients. the risk of major bleeding should be considered before and during therapy.	
John Roberts	Effective	Class IIb: Recommended, in Some Cases	In a placebo controlled trial of prophylaxis with apixaban at sub-therapeutic doses or placebo in patients receiving chemotherapy for cancer and at greater than average risk for venous thromboembolism , apixaban reduced venous thromboembolic events but increased bleeding events. Benefit was more common than harm. There was no significant difference in survival. Apixaban and low molecular weight heparins are options for venous thromboembolism in this patient population. Prophylaxis probably should be avoided in patients at high risk for bleeding, typically patients with esophageal and gastric cancer. Given the low baseline event rates (venous thromboembolism 10%, major bleeding 1.8%), no prophylaxis also reasonable.	
Richard LoCicero	Effective	Class IIb: Recommended, in Some Cases	Abixaban has been shown to prevent venous thromboembolism in patients with cancer undergoing chemotherapy. The risk of bleeding is increased.	