IBM Watson Health

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: August 18, 2020

PACKET: 1989

DRUG: Apixaban

USE: Thromboembolism of vein; 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
Agnelli, G, Becattini, C, Meyer, G, et al: Apixaban for the treatment of venous thromboembolism associated with cancer. N Engl J Med Apr 23, 2020; Vol 382, Issue 17; pp. 1599-1607.	This was an open-label, randomized-controlled non-inferiority trial that assessed noninferiority of apixaban to dalteparin for the treatment of venous thromboembolism in cancer patients. The risk of potential bias associated with randomization, allocation concealment, performance, detection, attrition and selective reporting were deemed low. Although the trial was open-label, the authors measured objective outcomes and employed a blinded central adjudication committee for outcome assessment.	S
McBane, R 2nd, Wysokinski, WE, Le-Rademacher, JG, et al: Apixaban and dalteparin in Active Malignancy Associated Venous Thromboembolism: The ADAM VTE Trial. J Thromb Haemost Oct 20, 2019; Vol Epub, p. Epub	This was an open-label, randomized-controlled trial that assessed apixaban versus dalteparin for the treatment of venous thromboembolism in cancer patients. The risk of potential bias associated with randomization, allocation concealment, performance, detection, attrition and selective reporting were deemed low. Although the trial was open-label, the authors measured objective outcomes and employed a blinded central adjudication committee for outcome assessment.	S
Agnelli, G, Buller, HR, Cohen, A, et al: Oral apixaban for the treatment of venous thromboembolism in cancer patients: results from the AMPLIFY trial. J Thromb Haemost Dec 2015; Vol 13, Issue 12; pp. 2187-2191.		2
Farge, D, Frere, C, Connors, JM, et al: 2019 international clinical practice guidelines for the treatment and prophylaxis of venous thromboembolism in patients with cancer. Lancet Oncol Oct 2019; Vol 20, Issue 10; pp. e566-e581.		1
Key, NS, Khorana, AA, Kuderer, NM, et al: Venous thromboembolism prophylaxis and treatment in patients with cancer: ASCO clinical practice guideline update. J Clin Oncol Aug 05, 2019; Vol Epub, p. Epub.		1

McCormack, T, Harrisingh, MC, Horner, D, et al: Venous Thromboembolism in Adults: Summary of Updated NICE Guidance on Diagnosis, Management, and Thrombophilia Testing. BMJ May 19, 2020; Vol Epub, p. Epub.		1

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		
Cynthia Beckett, 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 IIa: Recommended, in Most Cases		B
Jeffrey Klein	Evidence Favors Efficacy	Class IIa: Recommended, in Most Cases	The use of Apixaban to prevent VTE in patients with malignant neoplastic disease showed a good amount of efficacy. In a head to head comparison to another product, apixaban demonstrated less recurrence of VTE, as well as significantly less major bleeding episodes.	
John Roberts	Effective	Class IIb: Recommended, in Some Cases	In two randomized trials apixaban was similar or slightly superior to dalteparin in the prevention of venous thromboembolism with similar risks of bleeding in patients with cancer. In one trial patients preferred apixaban over dalteparin due to better convenience and fewer nuisance side effects. Differences in deaths due to any cause were not statistically significant, although in one trial the observed death rate with apixaban was higher. Apixaban is dosed twice daily. Other new orally active anticoagulants have also been shown to be superior to previous standard of care agents, and at least one of these is dosed once daily.	
Richard LoCicero	Effective	Class I: Recommended	Two randomized clinical trials have established the efficacy of Apixaban for the treatment of venous thromboembolism (VTE) in patients with cancer. VTE recurrence was lower than the control arms in both trials. No unexpected toxicity was observed.	