IBM Watson Health

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 3/29/2021

PACKET: 2075

DRUG: Abemaciclib

USE: Breast cancer; Early, hormone receptor-positive, HER2-negative, node-positive, high-risk, in combination with adjuvant endocrine therapy

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 *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
Johnston, SRD, Harbeck, N, Hegg, R, et al: Abemaciclib combined with endocrine therapy for the adjuvant treatment of HR+, HER2-, node-positive, high-risk, early breast cancer (monarchE). J Clin Oncol Dec 01, 2020; Vol 38, Issue 34; pp. 3987-3998.	This was an open-label, multicentre, randomized Phase 3 trial that investigated the addition of abemaciclib to standard adjuvant endocrine therapy in patients with HR+, HER2-, high-risk early breast cancer. The risk of potential bias associated with randomization, allocation concealment, performance, detection, attrition, and reporting were all deemed low. Funding bias due to the developer of the drug (Eli Lilly and Company) sponsoring the trial was also deemed low risk of bias.	S
Martin, JM and Goldstein, LJ: Profile of abemaciclib and its potential in the treatment of breast cancer. Onco Targets Ther Aug 29, 2018; Vol 11,pp. 5253-5259.		4

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 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 IIa: Recommended, in Most Cases	The use of abemaciclib with endocrine therapy to treat malignant breast cancer showed a favorable disease free survival over the control group. The degree of adverse events, especially of the more severe type is something that needs to be considered and regognized.	
Richard LoCicero	Effective	Class IIb: Recommended, in Some Cases	A single, phase III randomized clinical trial has established efficacy for the addition of abemaciclib to endocrine therapy in the adjuvant treatment of high risk breast cancer. The addition of abemaciclib was associated with adverse events (consistent with known toxicity of the drug). While this is the first published trial using this strategy, additional trials may help strengthen the role for this therapy.	
John Roberts	Evidence is Inconclusive	Class III: Not Recommended	Addition of abemaciclib to adjuvant endocrine therapy for early, hormone receptor-positive, HER2-negative, node-positive, high-risk breast cancer modestly improved disease-free survival and was associated with modest toxicity and some alleviation of endocrine therapy-induced toxicity. No difference in overall survival has been reported. It is not recommended as a standard of care at this time.	