IBM Watson Health

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: July 22, 2020

PACKET: 1973

DRUG: Capecitabine

USE: Malignant tumor of breast; Early, HER2-negative, postoperative monotherapy in patients with residual disease after neoadjuvant anthracycline/taxane-based treatment

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 *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
Chen, G, Guo, Z, Liu, M, et al: Clinical Value of Capecitabine-Based Combination Adjuvant Chemotherapy in Early Breast Cancer: A Meta-Analysis of Randomized Controlled Trials. Oncol Res Nov 02, 2017; Vol 25, Issue 9; pp. 1567-1578.		1
Natori, A, Ethier, J-L, Amir, E, et al: Capecitabine in early breast cancer: a meta-analysis of randomised controlled trials. Eur J Cancer May 2017; Vol 77, pp. 40-47.		1
Zhang, Z-C, Xu, Q-N, Lin, S-L, et al: Capecitabine in Combination With Standard (Neo)Adjuvant Regimens in Early Breast Cancer: Survival Outcome From a Meta-Analysis of Randomized Controlled Trials. PLoS One Oct 14, 2016; Vol 11, Issue 10; p. e0164663.		1
Masuda N, Lee SJ, Ohtani S, et al. Adjuvant Capecitabine for Breast Cancer after Preoperative Chemotherapy. N Engl J Med. 2017;376(22):2147-2159.	This was a multi-centre, open-label, phase 3 randomized controlled trial that investigated the use of capecitabine in patients with HER2-negative early breast cancer, with residual disease after receiving neoadjuvant chemotherapy. The risk of potential bias associated with randomization, allocation concealment, performance, detection, attrition, and reporting were all deemed low. Additional bias could be introduced by the trial being stopped early due to the pre-specified formal stopping rule.	S

Denduluri, N, Chavez-MacGregor, M, Telli, ML, et al: Selection of optimal adjuvant chemotherapy and targeted therapy for early breast cancer: ASCO clinical practice guideline focused update. J Clin Oncol Aug 10, 2018; Vol 36, Issue 23; pp. 2433-2443.		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		
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	Effective	Class IIa: Recommended, in Most Cases		B
Jeffrey Klein	Evidence Favors Efficacy	Class IIa: Recommended, in Most Cases	The use of Capeccitabine as monotherapy in early stage HER2-negative post chemo breast cancer patients shows a good degree of efficacy. Various levels of survival were documented as a benefit compared to the control group.The degree and prevalence of adverse effects was quite high and needs to be considered upon initiation of therapy	
John Roberts	Effective	Class IIa: Recommended, in Most Cases	The CREAT-X was conducted in Japan and South Korea. In the trial involving patients with HER2-negative breast cancer who had undergone neoadjuvant anthracycline/taxane based chemotherapy and surgery that revealed residual disease, improved outcomes including improved survival were seen in patients who received post-operative adjuvant capcitabine. Toxicity was moderate. Improvement was especially notable in patients with triple-negative cancer.	
Richard LoCicero	Effective	Class IIa: Recommended, in Most Cases	The addition of capecitabine after neoadjuvant anthracycline/taxane-based therapy and definitive surgery improved PFS and OS in patients with residual disease. The effect seems strongest in hormone receptor negative disease.	