IBM Watson Health

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 1/3/2020

PACKET: 1961

DRUG: Paclitaxel protein-bound

USE: Malignant tumor of breast; Neoadjuvant, in sequential combination with an anthracycline and cyclophosphamide

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, E, 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
Zong Y, Wu J, Shen K. Nanoparticle albumin-bound paclitaxel as neoadjuvant chemotherapy of breast cancer: a systematic review and meta-analysis. Oncotarget, 2017, Vol. 8, (No. 10), pp: 17360-17372		3
Brufsky, A: Nab-Paclitaxel for the treatment of breast cancer: an update across treatment settings. Exp Hematol Oncol Mar 22, 2017; Vol 6, Issue 1; p. 7.		2
Untch M, Jackisch C, Schneeweiss A, et al: Nab-paclitaxel versus solvent-based paclitaxel in neoadjuvant chemotherapy for early breast cancer (GeparSepto-GBG 69): A randomised, phase 3 trial. Lancet Oncol 17:345-356, 2016.	This was an open-label, randomized Phase 3 comparative trial that assessed neoadjuvant Nab-paclitaxel versus paclitaxel in patients with previously untreated breast cancer. The risk of potential bias associated with randomization, detection, attrition, and reporting were deemed low. The risk of bias associated with allocation concealment and performance were deemed high due to the open-label nature of the study, although this was somewhat mitigated by the use of central blinded review of the primary outcome.	S
Untch M, Jackisch C, Schneeweiss A: NAB-paclitaxel improves disease-free survival in early breast cancer: GBG 69–GeparSepto. J Clin Oncol 37:2226-2234,2019.	Study comments from Untch et al 2016 are relevant.	S

Gianni L, Mansutti M, Anton A, et al: Comparing neoadjuvant nab-paclitaxel vs paclitaxel both followed by anthracycline regimens in women With ERBB2/HER2-negative breast cancer-the evaluating treatment with neoadjuvant abraxane (ETNA) trial: A randomized phase 3 clinical trial. JAMA Oncol 4:302-308,2018.	This was an open-label, randomized Phase 3 comparative trial that assessed neoadjuvant Nab-paclitaxel versus paclitaxel in patients with HER2-negative breast cancer. The risk of potential bias associated with randomization, attrition, and reporting were deemed low. The risk of bias associated with allocation concealment, performance, and detection were deemed high due to the open-label nature of the study. Further potential bias could arise due to the study being funded by the marketer of the drug, Celgene.	S
Gianni L, Mansutti M, Anton A, et al: Event-free survival analysis of the prospectively randomized phase III ETNA study with neoadjuvant nab-paclitaxel (nab-P)versus paclitaxel (P) followed by anthracycline regimens in women with HER2-negative high-risk breast cancer. J Clin Oncol 37:515-515, 2019	Study comments from Gianni et al 2018 are relevant.	S
Furlanetto J, Jackisch C, Untch M, et al: Efficacy and safety of nab-paclitaxel 125 mg/m2and nab-paclitaxel 150 mg/m2compared to paclitaxel in early high-risk breast cancer: Results from the neoadjuvant randomized GeparSepto study (GBG 69). Breast Cancer Res Treat 163:495-506, 2017		3
Ayala de la Pena, F, Andres, R, Garcia-Saenz, JA, et al: SEOM clinical guidelines in early stage breast cancer (2018). Clin Transl Oncol Jan 2019; Vol 21, Issue 1; pp. 18-30.		4

Ross, M and Geyer Jr, CE: Nab-paclitaxel: a new standard of care in neoadjuvant therapy of high-risk early breast cancer. J Clin Oncol Sep 01, 2019; Vol 37, Issue 25; pp. 2196-2200.		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 Paclitaxel protein-bound to treat breast cancer patients in combination chemotherapy demonstrated an increased in long term survival rates. There was a distinct advantage using this form of paclitaxel over the solvent based product as well. The degree of neutropenia and neuropathy was to be considered in this therapy however.	
Richard LoCicero	Effective	Class IIb: Recommended, in Some Cases	Two randomized phase III trials compared nab-paclitaxel to solvent-based paclitaxel in the neoadjuvant treatment of non-metastatic breast cancer. In one of the trials, the pathologic complete response rate was improved with nab-paclitaxel; in the other there was no statistically significant difference. No unexpected toxicity was observed. The trials support the use of either nab-paclitaxel or solvent-based paclitaxel in this setting.	
John Roberts	Evidence is Inconclusive	Class IIb: Recommended, in Some Cases	In two randomized trials, nab-paclitaxel was equivalent or modestly more effective in prolonging disease free survival than solvent-based paclitaxel. Neither trial showed a benefit in overall survival, although these results are immature. Both agents are moderately toxic. Choice between the two agents should be based upon clinical, and, potentially, cost considerations.	