IBM Watson Health

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 4/30/2019

PACKET: 1867

DRUG: Paclitaxel Protein-Bound

USE: Malignant tumor of stomach, Refractory to first line fluoropyrimidine-containing chemotherapy

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, R, 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)]

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EVIDENCE CONSIDERED:

*to meet requirements 2 and 4

CITATION	STUDY-SPECIFIC COMMENTS	LITERATURE CODE
Shitara,K., Takashima,A., Fujitani,K., et al: Nab-paclitaxel versus solvent-based paclitaxel in patients with previously treated advanced gastric cancer (ABSOLUTE): an open-label, randomised, non-inferiority, phase 3 trial. Lancet Gastroenterol Hepatol Apr 2017; Vol 2, Issue 4; pp. 277-287.	This was a phase III, open-label, randomized non-inferiority trial that included patients at 72 centers in Japan. The non-inferiority margin was set at 1.25 according with historical data. The risks of potential bias associated with randomization, blinding of outcome assessment, attrition, and selective outcome reporting were all deemed low. The risks of potential bias associated with allocation concealment and blinding of participants and personnel were deemed high due to the open-label design of the trial. No additional biases were identified.	S
Sato,S., Kunisaki,C., Tanaka,Y., et al: A Phase II Study of Tri-weekly Low-dose Nab-paclitaxel Chemotherapy for Patients with Advanced Gastric Cancer. Anticancer Res Dec 2018; Vol 38, Issue 12; pp. 6911-6917.		2
Smyth,E.C., Verheij,M., Allum,W., et al: Gastric cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol Sep 2016; Vol 27, Issue suppl 5; pp. v38-v49.		2

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)

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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	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 (nab) to treat 2nd line stomach cancer patients seems to be effective. Good overall survival was documented. Less adverse effects if it is administered in lower once a week doses instead of an every 3 week regimen. Better overall response if given weekly.	
Richard LoCicero	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases	A single randomized non-inferiority trial demonstrated non-inferiority of nanoparticle albumin-bound paclitaxel over paclitaxel with respect to overall survival. No unexpected toxicity was observed.	

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John Roberts	Evidence is Inconclusive	Class III: Not Recommended	Although docetaxel and other chemotherapeutic agents have been shown to be effective as second line treatment for gastric cancer, the authors cite no such evidence for any paclitaxel formulation. Every third week protein bound paclitaxel (PPP) has not been shown to be non-inferior to solvent based paclitaxel (SBP) and is more toxic. Weekly PPP has been shown to be non-inferior, but not superior, to SBP and has a similar toxicty profile	

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