IBM Watson Health

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: July 15, 2020

PACKET: 1618

DRUG: Pertuzumab

USE: Malignant tumor of stomach or Gastroesophageal junction cancer; Metastatic, HER2-positive, in combination with trastuzumab and 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, 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
Tabernero, J, Hoff, PM, Shen, L, et al: Pertuzumab Plus Trastuzumab and Chemotherapy for HER2-positive Metastatic Gastric or Gastro-Oesophageal Junction Cancer (JACOB): Final Analysis of a Double-Blind, Randomised, Placebo-Controlled Phase 3 Study. Lancet Oncol Oct 2018; Vol 19, Issue 10; pp. 1372-1384.	This was a double-blind, placebo-controlled, randomized Phase 3 trial that assessed the addition of pertuzumab to trastuzumab and chemotherapy in patients with HER2-positive gastric or gastroesophageal cancer. The risk of potential bias associated with randomization, allocation concealment, performance, detection, attrition, and reporting were all deemed low. Additional funding bias could be introduced by manufacturing company sponsorship (F. Hoffmann-La Roche).	S
Liu, T, Qin, Y, Li, J, et al: Pertuzumab in Combination With Trastuzumab and Chemotherapy for Chinese Patients With HER2-positive Metastatic Gastric or Gastroesophageal Junction Cancer: A Subpopulation Analysis of the JACOB Trial. Cancer Commun (Lond) Jun 24, 2019; Vol 39, Issue 1; p. 38.	This was a subgroup analysis of the Tabernero et al 2018 study.	S
Shitara, K, Hara, H, Yoshikawa, T, et al: Pertuzumab Plus Trastuzumab and Chemotherapy for Japanese Patients With HER2-positive Metastatic Gastric or Gastroesophageal Junction Cancer: A Subgroup Analysis of the JACOB Trial. Int J Clin Oncol Oct 16, 2019; Vol Epub, p. Epub.	This was a subgroup analysis of the Tabernero et al 2018 study.	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		
Patricia Shofi, 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 is Inconclusive	Class III: Not Recommended		B
Jeffrey Klein	Evidence Favors Efficacy	Class IIa: Recommended, in Most Cases	The addition of Pertuzumab to a regimen that consists of trastuzumab and chemotherapy for gastric cancer patients, demonstrated an increased progression free survival. In addition increased overall survival was seen as well. Some patients exhibited a higher degree of serious adverse effects though.	
John Roberts	Ineffective	Class III: Not Recommended	A large, multi-national randomized trial showed no benefit and increased toxicity from addition of pertuzumab to trastuzumab and chemotherapy. Two small, post hoc subgroup analyses of two ethic groups were generally consistent with the overall findings.	

Richard LoCicero	Evidence is Inconclusive	Class III: Not Recommended	Clinical trial data does not support the use of pertuzumab to trastuzumab and chemotherapy in the treatment of metastatic her2-positive gastroesophageal cancer. There was no statistically significant improvement in PFS or OS endpoints. Toxicity was increased in the pertuzumab arms. Further studies are indicated to determine role for combination anti-HER2 therapy in this population.	