TRUVEN HEALTH ANALYTICS™
an IBM Company

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 9/1/2017

PACKET: 1476

DRUG: Pertuzumab

USE: Malignant tumor of breast, adjuvant, HER2 overexpression, 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, 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
von Minckwitz,G., Procter,M., de Azambuja,E., et al: Adjuvant pertuzumab and trastuzumab in early HER2 positive breast cancer. N Engl J Med Jul 13, 2017; Vol 377, Issue 2; pp. 122-131.	Comments: This was a randomized, multicenter, multinational, double-blind, placebo-controlled trial that included 549 sites in 43 countries. Key bias criteria evaluated were (1) random sequence generation of randomization; (2) lack of allocation concealment, (3) lack of blinding, (4) incomplete accounting of patients and outcome events, and (5) selective outcome reporting bias. The study was at low risk of bias for these key criteria, and no additional biases were identified.	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
Felicia Gelsey, MS	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
MICROMEDEX	Evidence is Inconclusive	Class lll: Not Recommended		B
John D Roberts	Evidence is Inconclusive	Class lll: Not Recommended	Pertuzumab showed a very modest improvement in invasive disease-free survival of marginal statistical significance (p<0.045 but CI including 1), a moderate increase in toxicity, and no survival benefit to date. The number needed to treat probably approaches 100. It should not be recommended at this time.	N/A
Jeffrey Klein	Ineffective	Class lll: Not Recommended	To subject these breast cancer patients to an additional therapy to their regimen without the potential of a "decent" survival benefit is not warranted. If you add in the fact that potential serious adverse effects may result further worsening quality of life or lead to other complications seems somewhat cruel.	N/A
Richard LoCicero	Evidence Favors Efficacy	Class llb: Recommended, In Some Cases	The addition of pertuzumab to chemotherapy and trastuzumab has been shown to reduce the risk of disease progression in a phase III trial. The 3-year disease free survival was 94.1 % vs. 93.2% (pertuzumab group vs. placebo group). Due to small magnitude of benefit, the addition of pertuzumab may be most appropriate in node-positive patients. Additionally, would limit use to those patients not receiving pertuzumab, neoadjuvantly.	N/A