TRUVEN HEALTH ANALYTICS™
an IBM Company

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 7/31/2017

PACKET: 1465

DRUG: Olaparib

USE: Metastatic breast cancer, HER2-negative, germline BRCA mutation-positive

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, A, 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
Robson,M., Im,S.A., Senkus,E., et al: Olaparib for metastatic breast cancer in patients with a germline BRCA mutation. N Engl.J Med Jun 04, 2017.	Comments: The OlympiAD trial was a randomized, open-label, multicenter, international, phase 3 trial. 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. The primary analysis was based on blinded independent central review. Additionally, the investigators confirmed the BRCA mutation with central testing, controlled for the Type 1 error rate, and conducted both power and sensitivity analyses. Only six patients did not receive treatment. A sensitivity analysis that excluded these six patients in the standard-therapy group who did not receive the assigned treatment showed similar results to the primary intent-to-treat analysis.	S
Robert,M., Frenel,J.-S., Gourmelon,C., et al: Olaparib for the treatment of breast cancer. Expert Opin Investig Drugs 2017; Vol 26, Issue 6; pp. 751-759.	Comments: Review article.	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
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	Effective	Class I: Recommended		B
John D Roberts	Effective	Class I: Recommended	A well done, industry sponsored study has shown that olaparib confers better disease control with less toxicity in comparison with three reasonable options for physician/patient directed single agent chemotherapy for patients with metastatic, HER2-negative, germline BRCApositive breast cancer. Survival was not improved, although this assessment outcome may have been confounded by differences in subsequent treatments.	N/A

Jeffrey Klein	Evidence is Inconclusive	Class lll: Not Recommended	The use of olaparib as a monotherapy agent for HER2-negative, germline BRCA mutation positive metastatic breast cancer patients did show some increase in progression free survival. The issues that prohibit its use include: Higher incidence of adverse effects than standard therapy, 25% pts tested required dose reduction, 40% pts required treatment interruption, the type of BRCA mutation studied was rare.	N/A
Richard LoCicero	Effective	Class l: Recommended	Clinical trial data supports the use of olaparib in patient with HER2-negative metastatic breast cancer and a germline BRCA mutation. A randomized trial compared olaparib monotherapy to physician's choice of capecitabine, eribulin or vinorelbine. Patient receiving olaparib had a median progression free survival of 7 months compared with 4.2 months for chemotherapy. Patient on olaparib had fewer adverse events as well.	N/A