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COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 12/5/16

PACKET: 1393

DRUG: Olaparib

USE: Malignant tumor of ovary, recurrent, platinum-sensitive, with at least 2 prior platinum-based chemotherapy regimens, as maintenance therapy

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)]

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EVIDENCE CONSIDERED:

*to meet requirements 2 and 4

CITATION	STUDY-SPECIFIC COMMENTS	LITERATURE CODE
Oza,A.M., Cibula,D., Benzaquen,A.O., et al: Olaparib combined with chemotherapy for recurrent platinum-sensitive ovarian cancer: A randomised phase 2 trial. The Lancet Oncology 2015; Vol 16, Issue 1; pp. 87-97.	Comments: This was an open-label, randomized, comparative, phase 2 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.	3
Ledermann,J., Harter,P., Gourley,C., et al: Olaparib maintenance therapy in platinum-sensitive relapsed ovarian cancer. New England Journal of Medicine 2012; Vol 366, Issue 15; pp. 1382-1392.	Comments: This was a double-blind, randomized, placebo-controlled, phase 2 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.	S
Ledermann,J., Harter,P., Gourley,C., et al: Olaparib maintenance therapy in patients with platinum-sensitive relapsed serous ovarian cancer: a preplanned retrospective analysis of outcomes by BRCA status in a randomised phase 2 trial. Lancet Oncol Jul 2014; Vol 15, Issue 8; pp. 852-861.		S

Ledermann JA, Harter P, Gourley C, et al. Overall survival in patients with platinum-sensitive recurrent serous ovarian cancer receiving olaparib maintenance monotherapy: an updated analysis from a randomised, placebo-controlled, double-blind, phase 2 trial. Lancet Oncol. 2016 Nov;17(11):1579-1589.		S
Matulonis,U.A., Harter,P., Gourley,C., et al: Olaparib maintenance therapy in patients with platinum-sensitive, relapsed serous ovarian cancer and a BRCA mutation: Overall survival adjusted for postprogression poly(adenosine diphosphate ribose) polymerase inhibitor therapy. Cancer Jun 15, 2016; Vol 122, Issue 12; pp. 1844-1852.		2
Tappenden,P., Harnan,S., Ren,S., et al: Olaparib for Maintenance Treatment of BRCA 1 or 2 Mutated, Relapsed, Platinum-Sensitive Ovarian, Fallopian Tube and Peritoneal Cancer in People Whose Relapsed Disease has Responded to Platinum-Based Chemotherapy: An Evidence Review Group Perspective of a NICE Single Technology Appraisal. PharmacoEconomics Aug 09, 2016		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 IIb: Recommended, In Some Cases		B
John D Roberts	Effective	Class IIb: Recommended, In Some Cases	Olaparib led to modest or moderate improvement in progression free survival, but little or no improvement in overall survival. Toxicity was common but tolerable. Treatment decisions should be based upon the trade-off between drug toxicity and earlier progression of cancer.	N/A
Jeffrey Klein	Effective	Class IIb: Recommended, In Some Cases	The authors of the trials clearly showed that Olaparib was effective only with BRCA mutated patients where both progression free survival and overall survival were demonstrated. Other types of patients did not have as favorable of an outcome. Adverse effects were rather high with this product and the authors seemed to downplay it.	N/A

Richard LoCicero	Evidence Favors Efficacy	Class IIb: Recommended, In Some Cases	While Olaparib maintenance treatment improved progression-free survival, it was associated with increased toxicity (over placebo) and no improvement in overall survival. The clinical value of progression-free survival may be meaningful to some. Additionally, the effectiveness of Olaparib maintenance treatment may be more significant in those patients with BRCA mutation.	N/A