IBM Watson Health

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 12/13/2019

PACKET: 1932

DRUG: Olaparib

USE: Malignant tumor of pancreas; Metastatic, deleterious or suspected deleterious germline BRCA1 or BRCA2 mutation, as maintenance therapy in patients who did not progress during first-line platinum-based 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)]

EVIDENCE CONSIDERED:

*to meet requirements 2 and 4

CITATION	STUDY-SPECIFIC COMMENTS	LITERATURE CODE
Golan T, Hammel P, Reni M, et al. Maintenance Olaparib for Germline BRCA-Mutated Metastatic Pancreatic Cancer. N Engl J Med 2019;381:317-27.	This was a double-blind, placebo-controlled, randomized Phase 3 trial that assessed olaparib maintenance therapy in metastatic pancreatic cancer patients with germline BRCA1/BRCA2 mutation. The risk of potential bias associated with randomization, allocation concealment, performance, detection, attrition, and reporting were deemed low. Further potential bias could arise due to the study being funded by the developers of the drug, AstraZeneca and Merck.	S
Kaufman,B., Shapira-Frommer,R., Schmutzler,R.K., et al: Olaparib monotherapy in patients with advanced cancer and a germline BRCA1/2 mutation. J Clin Oncol. Jan 20, 2015; Vol 33, Issue 3; pp. 244-250.		2
Golan, T, Kindler, HL, Park, JO, et al: Geographic and ethnic heterogeneity in the BRCA1/2 pre-screening population for the randomized phase III POLO study of olaparib maintenance in metastatic pancreatic cancer (mPC). J Clin Oncol 2018; Vol 36, Issue 15 Suppl 1; p. 4115.		2
Kowalewski,A., Szylberg,L., Saganek,M., et al: Emerging strategies in BRCA-positive pancreatic cancer. J Cancer Res Clin Oncol Aug 2018; Vol 144, Issue 8; pp. 1503-1507.		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
Megan Smith	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
IBM MICROMEDEX	Evidence Favors Efficacy	Class IIa: Recommended, in Most Cases		B
Richard LoCicero	Evidence Favors Efficacy	Class IIa: Recommended, in Most Cases	A randomized, double-blind, placebo-controlled phase III trial demonstrated a longer median progresion-free survival in patient with germline BRCA1 or BRCA2 mutation and metastatic pancreatic cancer. Unexpected toxicity was not observed.	
Jeffrey Klein	Evidence Favors Efficacy	Class IIa: Recommended, in Most Cases	The use of Olaparib as maintenance therapy to treat pancreatic cancer patients showed a good degree of progression free survival over placebo. The incidence of severe adverse effects was noted and this may limit its use.	
John Roberts	Effective	Class I: Recommended	In a single randomized, placebo controlled trial olaparib extended disease free survival and was well tolerated.	