IBM Watson Health

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: September 22, 2021

PACKET: 2119

DRUG: Niraparib

USE: Malignant tumor of ovary, Fallopian tube, or primary peritoneal cancer, recurrent, platinum-sensitive disease, in combination with bevacizumab

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
Tew, WP, Lacchetti, C, Ellis, A, et al: PARP Inhibitors in the Management of Ovarian Cancer: ASCO Guideline. J Clin Oncol Oct 20, 2020; Vol 38, Issue 30; pp. 3468-3493.		2
Hirte, H, Yao, X, Ferguson, SE, et al: An Ontario Health (Cancer Care Ontario) Clinical Practice Guideline: Consolidation or Maintenance Systemic Therapy for Newly Diagnosed Stage II, III, or IV Epithelial Ovary, Fallopian Tube, or Primary Peritoneal Carcinoma. Curr Oncol Mar 01, 2021; Vol 28, Issue 2; pp. 1114-1124.		2
Mirza, MR, Avall Lundqvist, E, Birrer, MJ, et al: Niraparib plus bevacizumab versus niraparib alone for platinum-sensitive recurrent ovarian cancer (NSGO-AVANOVA2/ ENGOT-ov24): a randomised, phase 2, superiority trial. Lancet Oncol Oct 2019; Vol 20, Issue 10; pp. 1409-1419.	This was an open-label, randomized phase 2 trial that assessed niraparib with or without bevacizumab in patients with platinum-sensitive recurrent ovarian cancer. The risk of bias associated with detection was deemed high risk due to the study employing an open-label design without the use of independent reviewers. The risk of potential bias associated with randomization, allocation concealment, performance, attrition and reporting were all deemed low risk.	S
Mirza, MR, Nyvang, G-B, Lund, B, et al: Final survival analysis of NSGO-AVANOVA2/ ENGOT-OV24: Combination of niraparib and bevacizumab versus niraparib alone as treatment of recurrent platinum-sensitive ovarian cancer -A randomized controlled chemotherapy-free study. J Clin Oncol 2020; Vol 38, Issue 15; p. 6012.		2

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 Roberts	None
		Todd Gersten	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 IIb: Recommended, in Some Cases		B
Todd Gersten	Evidence Favors Efficacy	Class IIa: Recommended, in Most Cases	The limited data available (a small phase II study) indicates that niraparib, when added to bevacizumab, prolongs PFS in the relapsed, platinum sensitive setting regardless of HR proficiency.	
Richard LoCicero	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases	Niraparib in combination with bevacizumab has been evaluated in the treatment of platinum-sensitive recurrent ovarian cancer in an open-label, randomized phase 2 trial. The combination of Niraparib/bevacizumab was associated tihe an improved progression free survival (11.9 months) vs. 5.5 months with single agent niraparib. Unexpected toxicity was not observed.	
John Roberts	Effective	Class IIb: Recommended, in Some Cases	In a large, multicenter, randomized trial in the treatment of recurrent, platinum-sensitive cancer of the ovary, fallopian tube, or peritoneum, niraparib + bevacizumab was modestly more effective than niraparib alone in terms of progression free survival. Toxicity was moderate. There was no bevacizumab alone arm, and the contribution of niraparib to the combination is unknown. Quality of life scores did not differ between niraparib + bevacizumab and niraparib alone even as more than half the nirparib alone patients had experienced progression of disease.	