IBM Watson Health

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: November 15, 2021

PACKET: 2142

DRUG: Olaparib

USE: Malignant tumor of breast; Early, HER2-negative, germline BRCA mutation-positive, high-risk, after (neo)adjuvant chemotherapy and local treatment (radiation) 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, E, 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
Tung, NM, Zakalik, D, Somerfield, MR, et al: Adjuvant PARP Inhibitors in Patients With High-Risk Early-Stage HER2-Negative Breast Cancer and Germline BRCA Mutations: ASCO Hereditary Breast Cancer Guideline Rapid Recommendation Update. J Clin Oncol Aug 03, 2021; Vol Epub, p. Epub.		S
Tutt, ANJ, Garber, JE, Kaufman, B, et al: Adjuvant olaparib for patients with BRCA1- or BRCA2-mutated breast cancer. N Engl J Med Jun 24, 2021; Vol 384, Issue 25; pp. 2394-2405.	This was a double-blind, placebo-controlled, randomized Phase III trial that assessed adjuvant olaparib in patients with HER2-negative early breast cancer who had received local treatment and (neo)adjuvant chemotherapy. The risk of potential bias associated with randomization, performance, detection, attrition, and reporting were deemed low.	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
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 IIa: Recommended, in Most Cases		B
Todd Gersten	Evidence Favors Efficacy	Class IIa: Recommended, in Most Cases	The available data reveal a modest improvement in long term survivorship (non significant trend) with the use of olaparib in high risk of recurrence breast cancer cases associated with BRCA muations.	
Richard LoCicero	Effective	Class I: Recommended	A phase III, double-blind, randomized trial of 1836 patients demonstrated efficacy of adjuvant olaparib therapy in her-2 negative breast cancer in patients with germline BRCA mutations. Unexpected toxicity was not observed.	
John Roberts	Evidence Favors Efficacy	Class IIa: Recommended, in Most Cases	In a randomized, placebo-controlled trial olarapinib improved disease free survival with minimal toxicity in patients with the following characteristics: - HER2-negative primary breast cancer - tumor with germline BRCA1or BRCA2 pathogenic or likely pathogenic variant - completed definitive local treatment without known persistent disease - completed neoadjuvant chemotherapy with residual invasive breast cancer in the breast or resected lymph nodes - if completed neoadjuvant chemotherapy and tumor hormone-receptor positive, there must have been less than a complete pathological response with CPS+EG score of 3 or higher. (American Joint Committee on Cancer CPS+EG (clinical and pathological stage and estrogen-receptor status and histologic grade) score) - if completed adjuvant chemotherapy and tumor hormone-receptor positive, there must have been four or more pathologically confirmed tumor positive lymph nodes - if completed adjuvant chemotherapy and tumor triple-negative, there must have been axillary node–positive disease or an invasive primary tumor measuring at least 2 cm on pathological analysis. Such patients have other treatment options.	