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Micromedex

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: September 9, 2022

OFF-LABEL ID #: 2442

DRUG NAME: Binimetinib

OFF-LABEL USE: Malignant tumor of ovary Fallopian tube, or primary peritoneal cancer, low-grade serous carcinoma, recurrent or persistent disease, as monotherapy

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, *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
Monk, BJ, Grisham, RN, Banerjee, S, et al: MILO/ENGOT-ov11: binimetinib versus physician's choice chemotherapy in recurrent or persistent low-grade serous carcinomas of the ovary, fallopian tube, or primary peritoneum. J Clin Oncol Nov 10, 2020; Vol 38, Issue 32; pp. 3753-3762.	This was an open-label, randomized-controlled trial that compared binimetinib to physician's choice chemotherapy in patients with recurrent or persistent low-grade serous carcinomas of the ovary, fallopian tube, or primary peritoneum. The risk of potential bias associated with randomization, allocation concealment, performance, detection, and reporting were deemed low. The risk of attrition bias was deemed moderate risk due to high attrition in both groups at the beginning of the trial period. No other sources of bias were found.	S
Grisham, RN, Moore, KN, Gordon, MS, et al: Phase Ib study of binimetinib with paclitaxel in patients with platinum-resistant ovarian cancer: final results, potential biomarkers, and extreme responders. Clin Cancer Res Nov 15, 2018; Vol 24, Issue 22; pp. 5525-5533.		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)

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CONTRIBUTORS:

*to meet requirement 3

PACKET PREPARATION	DISCLOSURES	EXPERT REVIEW	DISCLOSURES
Megan Smith	None		
Stacy LaClaire, PharmD	None		
Catherine Sabatos, PharmD	None		
		Todd Gersten	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 Is Inconclusive	Class IIb: Recommended, in Some Cases		B
Todd Gersten	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases	In multicenter randomized trial, Binimetinib demonstrated efficacy on par with standard of care chemotherapy. Consideration could be made for using the drug in this patient population when chemotherapy is not considered an appropriate option.	
Jeffrey Klein	Evidence Is Inconclusive	Class IIb: Recommended, in Some Cases	The use of Binimetinib in recurrent ovarian cancer patients did not demonstrate a significant gain in efficacy when compared to patients receiving chemotherapy. A predictor of better overall response appears to be seen in patients with a KRAS mutation positive biomarker. Further studies are needed.	

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Richard LoCicero	Evidence Is Inconclusive	Class III: Not Recommended	Binimetinib was evaluated in a randomized, controlled trial in patients with recurrent or persistent low-grade serous carcinoma of the ovary, fallopian tube or peritoneum. While anti-tumor effects were noted with binimetinib, the study did not meet its primary end point.	

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