

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: September 9, 2022

OFF-LABEL ID #: 2411

DRUG NAME: Trametinib Dimethyl Sulfoxide

OFF-LABEL USE: Malignant tumor of ovary; Or peritoneal cancer, low-grade serous carcinoma, recurrent, 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)]

*to meet requirements 2 and 4

CITATION	STUDY-SPECIFIC COMMENTS	LITERATURE CODE
<p>Gershenson, DM, Miller, A, Brady, WE, et al: Trametinib versus standard of care in patients with recurrent low-grade serous ovarian cancer (GOG 281/LOGS): an international, randomised, open-label, multicentre, phase 2/3 trial. Lancet Feb 05, 2022; Vol 399, Issue 10324; pp. 541-553.</p>	<p>This was an open-label, randomized-controlled trial that compared trametinib to physician's choice standard-of-care in patients with low-grade serous ovarian cancer. The risk of potential bias associated with randomization, allocation concealment, performance, attrition and reporting were deemed low. The risk of detection bias was deemed moderate risk due to the outcome being investigator-assessed. No other sources of bias were found.</p>	<p>S</p>
<p>Moujaber, T, Balleine, RL, Gao, B, et al: New therapeutic opportunities for women with low-grade serous ovarian cancer. Endocr Relat Cancer Nov 11, 2021; Vol 29, Issue 1; pp. R1-R16.</p>		<p>4</p>

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		
		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 Favors Efficacy	Class IIa: Recommended, in Most Cases		B
Jeffrey Klein	Evidence Favors Efficacy	Class I: Recommended	The use of Trametinib to treat recurrent malignant ovarian cancer patients demonstrated a higher degree of progression free survival when compared to the other treatment groups in this study. There was a slightly higher incidence of adverse effects with the Trametinib group	
Todd Gersten	Effective	Class IIa: Recommended, in Most Cases	Trametinib demonstrated an improvement in PFS and potentially OS (possible benefit hampered by cross-over) in a single randomized trial vs. standard chemo or hormonal therapy options in a heavily pretreated population	

Richard LoCicero	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases	Trametinib was evaluated in a phase II/III trial comparing it to one of five treatment options for the treatment of recurrent low-grade serous carcinoma of the ovary or peritoneum. Trametinib treatment was associated with improved progression free survival without unexpected toxicity.	
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