IBM Watson Health

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 11/5/2019

PACKET: 1927

DRUG: Sorafenib tosylate

USE: Malignant tumor of ovary; Primary peritoneal cancer, maintenance 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, 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
Herzog, TJ, Scambia, G, Kim, BG, et al:A randomized phase II trial of maintenance therapy with Sorafenib in front-line ovarian carcinoma. Gynecol Oncol Jul 2013; Vol 130, Issue 1; pp. 25-30.	This was a multi-center, double-blind, placebo-controlled, randomized Phase 2 trial that assessed sorafenib for maintenance of remission in ovarian cancer. The risk of potential bias associated with randomization, allocation concealment, performance, detection, attrition, and reporting were deemed low.	S
Chekerov,R., Hilpert,F., Mahner,S., et al: Sorafenib plus topotecan versus placebo plus topotecan for platinum-resistant ovarian cancer (TRIAS): a multicentre, randomised, double-blind, placebo-controlled, phase 2 trial. Lancet Oncol Sep 2018; Vol 19, Issue 9; pp. 1247-1258.	This was a multi-center, double-blind, placebo-controlled, randomized Phase 2 trial that assessed the addition of sorafenib to topotecan treatment for Platinum-resistant ovarian cancer. The risk of potential bias associated with randomization, allocation concealment, performance, detection, attrition, and reporting were deemed low. Another potential source of bias was identified; although the authors used consensus criteria for measuring disease response, no independent review of outcome was conducted, and the risk of potential bias was deemed unlcear risk.	S
Hainsworth, JD, Thompson, DS, Bismayer, JA, et al: Paclitaxel/carboplatin with or without sorafenib in the first-line treatment of patients with stage III/IV epithelial ovarian cancer: a randomized phase II study of the Sarah Cannon Research Institute. Cancer Med May 2015; Vol 4, Issue 5; pp. 673-681.	This was a multi-center, open-label, randomized Phase 2 trial that assessed the addition of sorafenib to paclitaxel/carboplatin for first-line treatment of stage III or IV ovarian cancer. The risk of potential bias associated with randomization and attrition were deemed low. The risk of potential bias associated with allocation concealment, performance, and detection were deemed high due to the open-label nature of the trial. The risk of potential bias due to selective reporting was deemed unclear risk due to lack of information provided by the study authors.	1

Schwandt, A, von Gruenigen, VE, Wenham, RM, et al: Randomized phase II trial of sorafenib alone or in combination with carboplatin/paclitaxel in women with recurrent platinum sensitive epithelialovarian, peritoneal, or fallopian tube cancer. Invest New Drugs Aug 2014; Vol 32, Issue 4; pp. 729-738.		3

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		
Valerie Haas, 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 is Inconclusive	Class III: Not Recommended		B
Jeffrey Klein	Evidence is Inconclusive	Class III: Not Recommended	The use of Sorafenib as single agent maintenance therapy in ovarian cancer patients who are in remission did not show favorable results. When used with topotecan, sorafenib showed a good degree of progression free survival. However the combination trial with topotecan was only 12 months. The incidence of significant adverse effects in both trials was very evident.	
Richard LoCicero	Ineffective	Class III: Not Recommended	Clinical trial data does not support the use of sorafenib in the maintenance treatment of ovarian or primary peritoneal cancer.	
John Roberts	Evidence is Inconclusive	Class III: Not Recommended	In a single randomized trial, women achieving a complete response following first line treatment of ovarian carcinoma with a platinum-based regimen did not benefit from sorafenib maintenance treatment, and that treatment was poorly tolerated. In another randomized trial, topotecan plus sorafenib induction followed by sorafenib maintenance was superior to topotecan alone for the treatment of platinum-resistant ovarian carcinoma. This suggests a role for sorafenib, but it does not clarify whether that role is in induction or maintenance or both.	