TRUVEN HEALTH ANALYTICS
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COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 9/6/2018

PACKET: 1736

DRUG: Pazopanib Hydrochloride

USE: Malignant tumor of ovary, Fallopian tube or primary peritoneal cancer, advanced, previously treated, in combination with paclitaxel

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)]

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EVIDENCE CONSIDERED:

*to meet requirements 2 and 4

CITATION	STUDY-SPECIFIC COMMENTS	LITERATURE CODE
Richardson,D.L., Sill,M.W., Coleman,R.L., et al: Paclitaxel with and without pazopanib for persistent or recurrent ovarian cancer: a randomized clinical trial. JAMA Oncol Feb 01, 2018; Vol 4, Issue 2; pp. 196-202.	Comments: This was a randomized, placebo-controlled, phase 2b trial. Key bias criteria evaluated were (1) random sequence generation of randomization; (2) lack of allocation concealment, (3) lack of blinding, (4) incomplete accounting of patients and outcome events, and (5) selective outcome reporting bias. The study was at low risk of bias for these key criteria, and no additional biases were identified.	S
Pignata,S., Lorusso,D., Scambia,G., et al: Pazopanib plus weekly paclitaxel versus weekly paclitaxel alone for platinum-resistant or platinum-refractory advanced ovarian cancer (MITO 11): a randomised, open-label, phase 2 trial.	Comments: This was a multicenter, open-label, randomized, phase 2 trial. Key bias criteria evaluated were (1) random sequence generation of randomization; (2) lack of allocation concealment, (3) lack of blinding, (4) incomplete accounting of patients and outcome events, and (5) selective outcome reporting bias. The study was at low risk of bias for these key criteria, however, there was possible high risk of bias for subjective outcomes due to the open-label design.	S
du,Bois A., Floquet,A., Kim,J.W., et al: Incorporation of pazopanib in maintenance therapy of ovarian cancer. J Clin Oncol Oct 20, 2014; Vol 32, Issue 30; pp. 3374-3382.	Comments: This was an international, randomized, double-blind, placebo-controlled, phase III trial. Key bias criteria evaluated were (1) random sequence generation of randomization; (2) lack of allocation concealment, (3) lack of blinding, (4) incomplete accounting of patients and outcome events, and (5) selective outcome reporting bias. The study was at low risk of bias for these key criteria, and no additional biases were identified.	1
Floquet,A., Vergote,I., Colombo,N., et al: Progression-free survival by local investigator versus independent central review: comparative analysis of the AGO-OVAR16 Trial. Gynecol.Oncol Jan 2015; Vol 136, Issue 1; pp. 37-42.		1

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Friedlander,M., Rau,J., Lee,C.K., et al: Quality of life in patients with advanced epithelial ovarian cancer (EOC) randomized to maintenance pazopanib or placebo after first-line chemotherapy in the AGO-OVAR 16 trial. Measuring what matters-patient-centered end points in trials of maintenance therapy. Ann Oncol 2018; Vol 29, Issue 3; pp. 737-743.		1
Harter,P., Johnson,T., Berton-Rigaud,D., et al: BRCA1/2 mutations associated with progression-free survival in ovarian cancer patients in the AGO-OVAR 16 study. Gynecol.Oncol. Mar 2016; Vol 140, Issue 3; pp. 443-449.		1
Kim,J.W., Mahner,S., Wu,L.Y., et al: Pazopanib maintenance therapy in East Asian women with advanced epithelial ovarian cancer: results from AGO-OVAR16 and an East Asian Study. Int J Gynecol.Cancer Jan 2018; Vol 28, Issue 1; pp. 2-10.		1
Friedlander,M., Hancock,K.C., Rischin,D., et al: A Phase II, open-label study evaluating pazopanib in patients with recurrent ovarian cancer. Gynecol.Oncol Oct 2010; Vol 119, Issue 1; pp. 32-37.		3

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Komiyama,S., Katabuchi,H., Mikami,M., et al: Japan Society of Gynecologic Oncology guidelines 2015 for the treatment of ovarian cancer including primary peritoneal cancer and fallopian tube cancer. Int J Clin Oncol Jun 2016; Vol 21, Issue 3; pp. 435-446.		4

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
Felicia Gelsey, MS	None		
Stacy LaClaire, PharmD	None		
Catherine Sabatos, 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
MICROMEDEX	Evidence is Inconclusive	Class III: Not Recommended		A
John D Roberts	Ineffective	Class III: Not Recommended	In two randomized trials the addition of pazopanib to paclitaxel for the treatment of ovarian and related cancers was associated with no improvement or modest improvement in progression free and overall survival and significant toxicity.	N/A
Jeffrey Klein	Evidence is Inconclusive	Class III: Not Recommended	The use of Pazopanib in combination with paclitaxel to treat advanced ovarian cancer showed a modest progression free survival in one study. The other study showed no advantage. Severe adverse effects were reported in both trials when pazopanib was added.	N/A

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Richard LoCicero	Evidence is Inconclusive	Class III: Not Recommended	Insufficient clinical trial data exists to support the use of pazopanib in combination with paclitaxel. Of two trials presented (comparing single agent paclitaxel to the pazopanib/paclitaxel combination), one demonstrated no improvement in progression free survival (PFS) or overall survival (OS); but increased toxicity in the pazopanib arm. The second study (an open-label, randomized, phase 2 study) demonstrated inproved PFS but not OS, with increased toxicity over single agent paclitaxel.	N/A

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