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COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 8/28/2017

PACKET: 1474

DRUG: Pazopanib

USE: Gastrointestinal stromal tumor, metastatic or advanced, after failure of imatinib and sunitinib

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
Mir O et al. Pazopanib plus best supportive care versus best supportive care alone in advanced gastrointestinal stromal tumours resistant to imatinib and sunitinib (PAZOGIST): a randomised, multicentre, open-label phase 2 trial	Comments: This was a multicenter, open-label, phase 2 study. 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. A major caveat of the study was that 88% of the patients in the best supportive care group crossed over to pazopanib treatment after disease progression. The authors presented results on both median post-switch progression-free survival and median post-switch overall survival for this group of patients.	S
Ganjoo KN, et al. A multicenter phase II study of pazopanib in patients with advanced gastrointestinal stromal tumors (GIST) following failure of at least imatinib and sunitinib.		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
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 Favors Efficacy	Class IIb:Recommended, In Some Cases		B
John D Roberts	Evidence Favors Efficacy	Class IIb: Recommended, In Some Cases	In a randomized trial pazopanib showed a modest increase in disease-free survival compared to best supportive care in patients with GIST previously treated with imatinib and sunitinib. Serious toxicities in including potentially lethal toxicities were common. A previous single arm phase II trial suggested that the benefit of pazopanib was much less than that of either imatinib or sunitinib when the agents were given in the order imatinib, sunitinib, pazopanib, and also showed a significant toxicity profile. Thromboembolic events were relatively common, suggesting that patients with a previous history of thrombosis may be at greater risk for toxicity.	N/A

Jeffrey Klein	Evidence Favors Efficacy	Class lll: Not Recommended	The use of pazopanib in gastrointestinal stromal tumor patients who have failed with imatinib and sunitinib shows some slight increase in progression free survival. The very small study compared patients who received the drug versus those who did not. This 4th line agent had too high of an adverse effect profile to warrant its use, The authors of the study seem to downplay the rate and severity of these side effects.	N/A
Richard LoCicero	Evidence is Inconclusive	Class llb: Recommended, In Some Cases	Available treatment of gastrointestinal stromal tumors is limited after failure of imatinib and sunitinib. Pazopanib was compared to best supportive care with a 1.1 month advantage in progression-free survival (3.4 vs. 2.3) in this population.	N/A