COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 11/17/2020

PACKET: 2057

DRUG: Pazopanib

USE: Renal cell carcinoma, Adjuvant therapy following nephrectomy in patients at high risk for recurrence

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
Hotte, SJ, Kapoor, A, Basappa, NS, et al: Management of advanced kidney cancer: Kidney Cancer Research Network of Canada (KCRNC) consensus update 2019. Can Urol Assoc J Oct 2019; Vol 13, Issue 10; pp. 343-354.		2
Lazaro, M, Valderrama, BP, Suarez, C, et al: SEOM clinical guideline for treatment of kidney cancer (2019). Clin Transl Oncol Feb 2020; Vol 22, Issue 2; pp. 256-269.		2
Ljungberg, B, Albiges, L, Abu-Ghanem, Y, et al: European Association of Urology Guidelines on Renal Cell Carcinoma: The 2019 Update. Eur Urol May 2019; Vol 75, Issue 5; pp. 799-810.		S
Motzer, RJ, Haas, NB, Donskov, F, et al: Randomized phase III trial of adjuvant pazopanib versus placebo after nephrectomy in patients with localized or locally advanced renal cell carcinoma. J Clin Oncol Dec 10, 2017; Vol 35, Issue 35; pp. 3916-3923.	This was a placebo-controlled, randomized phase III trial that assessed adjuvant pazopanib in patients with renal cell carcinoma at high risk of relapse after nephrectomy. The risk of potential bias associated with randomization and allocation concealment were deemed low. The risk of bias associated with performance and detection were deemed unclear due to lack of information about any blinding methods. Attrition bias was deemed high risk due to severe imbalance in attrition rates between treatment and control groups, and selective reporting bias was deemed high risk due to changes to the protocol after the commencement of the study.	S

Sternberg, CN, Donskov, F, Haas, NB, et al: Pazopanib exposure relationship with clinical efficacy and safety in the adjuvant treatment of advanced renal cell carcinoma. Clin Cancer Res Jul 01, 2018; Vol 24, Issue 13; pp. 3005-3013.		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)

CONTRIBUTORS:

*to meet requirement 3

PACKET PREPARATION	DISCLOSURES	EXPERT REVIEW	DISCLOSURES
Megan Smith	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
IBM MICROMEDEX	Ineffective	Class III: Not Recommended		B
Jeffrey Klein	Ineffective	Class III: Not Recommended	The use of Pazopanib to prevent recurrence of renal cell cancer in patients following nephrectomy showed no survival benefits when compared to placebo. In addition the incidence of serious adverse effects such as elevated liver enzymes was noted.	
John Roberts	Ineffective	Class III: Not Recommended	In a single randomized placebo controlled trial, adjuvant therapy with pazopanib at tolerable doses did not improve outcomes.	
Richard LoCicero	Ineffective	Class III: Not Recommended	A phase III trial evaluated the efficacy and safety of pazopanib versus placebo in patients with renal cell carcinoma at high risk for relapse after nephrectomy. Pazopanib showed no benefit over placebo.	