IBM Watson Health

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 11/17/2020

PACKET: 2058

DRUG: Sorafenib

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
Haas,N.B., Manola,J., Uzzo,R.G., et al: Adjuvant sunitinib or sorafenib for high-risk, non-metastatic renal-cell carcinoma (ECOG-ACRIN E2805): a double-blind, placebo-controlled, randomised, phase 3 trial. Lancet May 14, 2016; Vol 387, Issue 10032; pp. 2008-2016.	This was a triple-arm, double-blind, placebo-controlled, randomized phase III trial that assessed adjuvant sorafenib or sunitinib in patients with renal cell carcinoma at high risk of relapse after nephrectomy. The risk of potential bias associated with randomization, allocation concealment, performance, and detection were deemed low. 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

Haas, NB, Manola, J, Dutcher, JP, et al: Adjuvant Treatment for High-Risk Clear Cell Renal Cancer: Updated Results of a High-Risk Subset of the ASSURE Randomized Trial. JAMA Oncol Sep 01, 2017; Vol 3, Issue 9; pp. 1249-1252.	This was a subgroup analysis of the Haas et al 2016 published trial.	S
Blinman, PL, Davis, ID, Martin, A, et al: Patients' preferences for adjuvant sorafenib after resection of renal cell carcinoma in the SORCE trial: what makes it worthwhile?. Ann Oncol Feb 01, 2018; Vol 29, Issue 2; pp. 370-376.		1

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 Sorafenib to prevent recurrence of renal cell cancer in patients following nephrectomy showed no survival benefits when compared to placebo or another similar medication. In addition the incidence of serious adverse effects warranted dose reduction or discontinuation of therapy	
John Roberts	Ineffective	Class III: Not Recommended	Several studies indicate that sorafenib is ineffective as adjuvant therapy following resection of renal cell carcinoma.	
Richard LoCicero	Ineffective	Class III: Not Recommended	Two randomized clinical trials have evaluated the use of sorafenib for the adjuvant treatment of renal cell carcinoma after nephrectomy. Neither demonstrated efficacy in this setting.	