



COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 11/17/2020

PACKET: 2045

DRUG: Axitinib

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
Gross-Goupil, M, Kwon, TG, Eto, M, et al: Axitinib versus placebo as an adjuvant treatment of renal cell carcinoma: results from the phase III, randomized ATLAS trial. Ann Oncol Dec 01, 2018; Vol 29, Issue 12; pp. 2371-2378.	This was a double-blind, placebo-controlled, randomized phase III trial that assessed adjuvant axitinib in patients with newly-diagnosed renal cell carcinoma with prior nephrectomy. The risk of potential bias associated with randomization, allocation concealment, performance, detection, attrition, and reporting were deemed low. An additional source of bias associated with funding was deemed low risk.	S
Laguna, MP: Re: Axitinib versus placebo as an adjuvant treatment of renal cell carcinoma: results from the phase III, randomized ATLAS Trial. J Urol Jul 2019; Vol 202, Issue 1; pp. 27-28.		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)



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				B
Jeffrey Klein	Ineffective	Class III: Not Recommended	The use of Axitinib to prevent recurrence of renal cell cancer in patients following nephrectomy showed no benefit in disease free survival when compared to placebo. In addition the incidence of serious adverse effects was prevalent.	
John Roberts	Ineffective	Class III: Not Recommended	In a single randomized placebo controlled trial axitinib was not associated with improvement in disease free survival and was associated with moderate toxicity. Exploratory analysis in a high risk subgroup suggested benefit, but this should not be a basis for clinical decision-making.	
Richard LoCicero	Evidence is Inconclusive	Class III: Not Recommended	A phase III randomized, double-blind trial evaluated the use of axitinib as adjuvant therapy in renal cell carcinoma. The trial was stopped due to futility. In a high risk population, a disease free survival benefit was observed, but evidence is inconclusive in the context of an incomplete trial with immature overall survival data.	