

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: December 4, 2023

OFF-LABEL ID #: 2630

DRUG NAME: Nivolumab

OFF-LABEL USE: Renal cell carcinoma Adjuvant treatment, in patients at moderate or high risk of recurrence following nephrectomy; in combination with ipilimumab

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, 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	LITERATURE CODE
Motzer, RJ, Russo, P, Grunwald, V, et al: Adjuvant nivolumab plus ipilimumab versus placebo for localised renal cell carcinoma after nephrectomy (CheckMate 914): a double-blind, randomised, phase 3 trial. Lancet Mar 11, 2023; Vol 401, Issue 10379; pp. 821-832. Pubmed ID: 36774933	S
Bedke, J, Albiges, L, Capitanio, U, et al: The 2022 Updated European Association of Urology Guidelines on the use of adjuvant immune checkpoint inhibitor therapy for renal cell carcinoma. Eur Urol Jan 2023; Vol 83, Issue 1; pp. 10-14. Pubmed ID: 36511268	4
Méndez-Vidal MJ, Lázaro Quintela M, Lainez-Milagro N, Perez-Valderrama B, Suárez Rodríguez C, Arranz Arijá JÁ, Peláez Fernández I, Gallardo Díaz E, Lambea Sorrosal J, González-Del-Alba A. SEOM SOGUG clinical guideline for treatment of kidney cancer (2022). Clin Transl Oncol. 2023 Sep;25(9):2732-2748. doi: 10.1007/s12094-023-03276-5. Epub 2023 Aug 9. PMID: 37556095	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
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
MERATIVE MICROMEDEX	Ineffective	Class III: Not Recommended		B
Todd Gersten	Ineffective	Class III: Not Recommended	The combination of Ipi-Nivo failed to reduce recurrence rates when used adjuvantly following nephrectomy for carcinoma in a large randomized study.	
Richard LoCicero	Ineffective	Class III: Not Recommended	Adjuvant nivolumab in combination with ipilimumab was evaluated in the adjuvant treatment of renal cell carcinoma in a double-blind, placebo-controlled, randomized trial. 816 patients were enrolled: 405 received nivolumab + ipilimumab, 411 received placebo. No statistically significant difference in median disease-free survival was observed between the two groups.	

Jeffrey Klein	Ineffective	Class III: Not Recommended	The use of nivolumab in combination with ipilumab to treat post nephrectomy renal cell carcinoma patients did not show any advantage over placebo in the disease free survival category. In addition the degree of adverse effects were significantly higher than the placebo group.	
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