COMPENDIA TRANSPARENCY TRACKING FORM

DATE: February 5, 2024

OFF-LABEL ID #: 2648

DRUG NAME: Nivolumab

OFF-LABEL USE: Merkel cell carcinoma

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, A, R *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
Kim, S, Wuthrick, E, Blakaj, D, et al: Combined nivolumab and ipilimumab with or without stereotactic body radiation therapy for advanced Merkel cell carcinoma: a randomised, open label, phase 2 trial. Lancet Sep 24, 2022; Vol 400, Issue 10357; pp. 1008-1019. Pubmed ID: 36108657	S
Topalian, SL, Bhatia, S, Amin, A, et al: Neoadjuvant nivolumab for patients with resectable merkel cell carcinoma in the CheckMate 358 trial. J Clin Oncol Aug 01, 2020; Vol 38, Issue 22; pp. 2476-2487. Pubmed ID: 32324435	S
ClinicalTrials.gov: An investigational immuno-therapy study to investigate the safety and effectiveness of nivolumab, and nivolumab combination therapy in virus-associated Tumors (CheckMate358). US National Library of Medicine (NLM). Bethesda, MD. Nov 13, 2023. Available from URL: https://clinicaltrials.gov/study/NCT02488759?term=NCT02488759&rank=1&tab=results.	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	Effective	Class I: Recommended		B
Todd Gersten	Effective	Class I: Recommended	In this relatively rare disease, the very limited evidence with nivolumab is consistent with that recognized with other immune checkpoint inhibitors in this disease (i.e. ability to induce high response rates, often complete, and prolonged disease control).	
Jeffrey Klein	Evidence Favors Efficacy	Class IIa: Recommended, in Most Cases	The use of nivolumab with or without ipiliumab produced a good overall treatment response in patients who have merkel cell carcinoma. The response was significantly more evident in patients who did not receive previous immune therapies. The incident of higher grade adverse effects need to be considered though.	

Warren Brenner	Effective	Class I: Recommended	MCC is a rare malignancy with aggressive biology and few good therapeutic options. It also tends to occur in the elderly where their ability to tolerate chemotherapy is often compromised. Also due to the relative rarity of MCC it is difficult to conduct large phase III randomised clinical trials. With all that said I believe this data is very encouraging and enough in my opinion to establish either single agent Nivo or Ipi/Nivo as legitimate treatment options based on the 100% RR, durable responses and realtively good safety data. I believe much more promising and active compared historially to platinum based chemotherpay therefore class I recommendation in my opinion.	