

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: February 20, 2024

OFF-LABEL ID #: 2647

DRUG NAME: Nivolumab

OFF-LABEL USE: Liver cell carcinoma Advanced

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, A, 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	LITERATURE CODE
Yau, T, Park, J-W, Finn, RS, et al: Nivolumab versus sorafenib in advanced hepatocellular carcinoma (CheckMate 459): a randomised, multicentre, open-label, phase 3 trial. Lancet Oncol Jan 2022; Vol 23, Issue 1; pp. 77-90. Pubmed ID: 34914889	S
Yau, T, Zagonel, V, Santoro, A, et al: Nivolumab plus cabozantinib with or without ipilimumab for advanced hepatocellular carcinoma: results from cohort 6 of the CheckMate 040 trial. J Clin Oncol Mar 20, 2023; Vol 41, Issue 9; pp. 1747-1757. Pubmed ID: 36512738	S
Gordon, JD, Kennedy, EB, Abou-Alfa, GK, et al: Systemic therapy for advanced hepatocellular carcinoma: ASCO Guideline. J Clin Oncol Dec 20, 2020; Vol 38, Issue 36; pp. 4317-4345. Pubmed ID: 33197225	2
No authors listed: Correction: Nivolumab after selective internal radiation therapy for the treatment of hepatocellular carcinoma: a phase 2, single-arm study. J Immunother Cancer Mar 2023; Vol 11, Issue 3; p. e005457corr1. Pubmed ID: 36898738 Publication Types: Published Erratum CC	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
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	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases		B
Warren Brenner	Evidence is Inconclusive	Class IIb: Recommended, in Some Cases	Although Nivo has activity in HCC we have 2 FDA approved options that have proven to be more effective than sorafenib in phase III randomised trials with atezo/bev and the STRIDE regimen. Therefore do not believe we need another single agent CPI therapy-may considered single agent nivo if pt has poor baseline liver functions - CBS or worse. The data with ipi/nivo or nivo/cabo is too early to draw any conclusions but again do not believe adds substantially to current therapeutic options.	
Jeffrey Klein	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases	The use of nivolumab in advance liver cell carcinoma patients showed a good degree of overall survival in these studies. However the high grade of serious adverse effects need to be taken into consideration before therapy starts.	

<p>Todd Gersten</p>	<p>Evidence Favors Efficacy</p>	<p>Class IIb: Recommended, in Some Cases</p>	<p>In a large randomized trial, as a single agent vs. SOC sorafenib, nivolumab offers no statistical improvement in overall survivorship. However, compared historically to placebo (OS 8months), nivolumab does offer an OS advantage and could be considered an alternative to sorafenib in patients not able to tolerate the latter. Meanwhile, the true benefits of the addition of nivolumab to drug combinations cannot be ascertained in the absence of control arms (i.e. nivo+cabo vs. nivo+cabo+ipi versus cabo alone) and in the setting of such a small trial/limited data.</p>	
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