merative

Micromedex

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: May 19, 2025

OFF-LABEL ID #: 2714

DRUG NAME: Dostarlimab-gxly

OFF-LABEL USE: Nonsquamous nonsmall cell neoplasm of lung Metastatic disease without genomic aberrations, first-line treatment in combination with pemetrexed and platinum chemotherapy

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, 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
Lim SM, Peters S, Ortega Granados AL, et al. Dostarlimab or pembrolizumab plus chemotherapy in previously untreated metastatic non-squamous non-small cell lung cancer: the randomized PERLA phase II trial. Nat Commun. 2023 Nov 11;14(1):7301. doi: 10.1038/s41467-023-42900-4. PMID: 37951954	S
Reck M, Granados ALO, de Marinis F, et al. Patient-reported outcomes in patients with metastatic non-squamous non-small cell lung cancer from the randomized Phase II PERLA trial comparing first-line chemotherapy plus dostarlimab or pembrolizumab. Eur J Cancer. 2024 Nov;212:115050. doi: 10.1016/j.ejca.2024.115050. Epub 2024 Sep 29. PMID: 39378565.	3
Moreno V, Roda D, Pikiel J, et al. Safety and Efficacy of Dostarlimab in Patients With Recurrent/Advanced Non-small Cell Lung Cancer: Results from Cohort E of the Phase I GARNET Trial. Clin Lung Cancer. 2022 Nov;23(7):e415-e427. doi: 10.1016/j.cllc.2022.05.013. Epub 2022 May 23. PMID: 35729005.	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
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 IIa: Recommended, in Most Cases		B
Jeffrey Klein	Evidence Favors Efficacy	Class IIa: Recommended, in Most Cases	The use of Dostarlimab in combination with 2 other agents to treat first line NSCLC, showed good overall response rate, good progression free survival, and good overall survival. The results exceeded a pembrolizumab combination regimen. The adverse effect profile was similar to the pembrolizumab group	

Warren Brenner	Evidence Is Inconclusive	Class III: Not Recommended	This was a relatively large phase II randomized trial asking the question of whether Dostarlimab(a PD-1 inhibitor) may be more effective than pembro(a PDL-1 inhibitor). The primary end point of ORR is a soft endpoint and given the similarity between the 2 arms as far as ORR I rated the evidence as inconclusive and gave it a Class III recommendation as I don't believe it changes the current standard of care which are based on much larger phase III randomized trials. Although some finding are provocative they were not the primary end point of the study and some of the data such as some prolongation of PFS and OS the data are immature and numbers small and hypothesis generating rather than conclusive. The higher RR in patients with TPS scores >1% are also provocative but again numbers are small and were not the primary endpoint therefore many of the findings in this study are interesting but not practice changing	
Todd Gersten	Effective	Class I: Recommended	Dostarlimab, in combination with chemotherapy, showed equivalent (with trends toward improved) efficacy endpoints as compared to pembrolizumab, in combination with chemotherapy, in a randomized double blinded study. Considering that pembrolizumab, with chemotherapy, is considered to be the modern day standard regimen in this setting, dostarlimab merits a Class I recommendation	