

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: May 29, 2026

OFF-LABEL ID #: MDXOLS-471

DRUG NAME: Retifanlimab

OFF-LABEL USE: Non-small cell lung cancer, Stage IV, first-line in combination with platinum-based 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
Lu S, Vynnychenko O, Kulyaba Y, et al. Retifanlimab versus placebo in combination with platinum-based chemotherapy in patients with first-line non-squamous or squamous metastatic non-small-cell lung cancer (POD1UM-304): a phase 3, multiregional, placebo-controlled, double-blind, randomised study. <i>Lancet Respir Med.</i> 2025;13(12):1096-1107. PMID: 40983066.	S

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		

ASSIGNMENT OF RATINGS:

*to meet requirement 4

	EFFICACY	STRENGTH OF RECOMMENDATION	COMMENTS	STRENGTH OF EVIDENCE
MERATIVE MICROMEDEX	Effective	Class IIa: Recommended, in Most Cases		B
Jeffrey Klein	Evidence Favors Efficacy	Class IIa: Recommended, in Most Cases	The use of Retifanlimab with platinum based chemotherapy in stage 4 first line NSLC patients demonstrated higher overall survival rates than the group without Retifanlimab. Adverse effects were more apparent in the Retifanilumab group.	
Todd Gersten	Effective	Class I: Recommended	Retifanlimab, in a randomized controlled trial, demonstrated improvement in all clinically significant endpoints versus placebo when added to doublet platinum based chemotherapy.	
Warren Brenner	Effective	Class IIa: Recommended, in Most Cases	This large phase III randomized clinical trial showed that the addition of Retifanlimab in patients with advanced NSCLC including adenocarcinoma and squamous histologies was effective with improved RR, PFS and OS with better results in patients with higher TPS scores. The study results warrant an effective rating but as this does not impact current management as we already use chemo + 10 in this patient population I gave it a lower strength of recommendation as this is already a crowded market space and doesn't add anything to the current SOC options already available.	

