merative

Micromedex

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: April 17, 2024

OFF-LABEL ID #: 2696

DRUG NAME: Toripalimab-tpzi

OFF-LABEL USE: Non-small cell lung cancer Advanced disease, first-line therapy in combination with platinum-containing doublet chemotherapy followed by toripalimab maintenance therapy (with pemetrexed for nonsquamous cell disease)

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
Wang Z, Wu L, Li B, et al. Toripalimab Plus Chemotherapy for Patients With Treatment-Naive Advanced Non-Small-Cell Lung Cancer: A Multicenter Randomized Phase III Trial (CHOICE-01). J Clin Oncol. 2023;41(3):651-663. doi: 10.1200/JCO.22.00727. Epub 2022 Oct 7. PMID: 36206498; PMCID: PMC9870236.	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		
		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
Todd Gersten	Evidence Favors Efficacy	Class IIa: Recommended, in Most Cases	In lung nonsquamous carcinoma the addition of toripalimab to first-line platinum doublet and pemetrexed maintenance improved efficacy end points including response rate, PFS and OS. Reservations in evaluating the true efficacy are due to: 1) The study was conducted only in Asia and 2) The control arm OS was 17 months yet the same control arm on KEYNOTE-189, a global study, was just around 10 months.	

Jeffrey Klein	Evidence Favors Efficacy	Class IIa: Recommended, in Most Cases	The use of Toripalimab with platinum chemotherapy for first line NSCLC patients showed a dramatic increase in progression free survival as well as overall survival. The patients who demonstrated the best results were non-squamous and did not have mutations. Some higher grade adverse events were noted in the Toripalimab group.	
Warren Brenner	Effective	Class IIa: Recommended, in Most Cases	This was a large well conducted phase III randomized trial using a chemotherapy backbone commonly used. Advantages of the trial include its large size, heterogenous population and including both SC and adenocarcinoma populations. The Hazard ration on the forest plot shows advantages for the combination with Toripalimab in all subgroups analyzed verifying its effectiveness with clinically meaningful differences in PFS and OS. I assigned it a Class IIA recommendation rather than class I for 2 main reasons - it was solely conducted in China so we don't know if this will be as effective in a western population. The second and main reason is the suboptimal comparator arm. In the modern era we use chemo + checkpoint inhibitor in patients with non actionable oncogenic drivers so how this regimen would compare to a modern regimen is unclear.	