merative

Micromedex

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: April 17, 2024

OFF-LABEL ID #: 2669

DRUG NAME: Toripalimab-tpzi

OFF-LABEL USE: Non-small cell lung cancer Neoadjuvant therapy in combination with platinum-containing doublet chemotherapy, followed by one adjuvant cycle with combination therapy, then continued as single-agent maintenance therapy

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, Zhang W, Wu L, et al. Perioperative Toripalimab Plus Chemotherapy for Patients With Resectable Non-Small Cell Lung Cancer: The Neotorch Randomized Clinical Trial. JAMA. 2024;331(3):201-211. doi: 10.1001/jama.2023.24735. PMID: 38227033; PMCID: PMC10792477.	S
Hou H, Wang Y, Sun D, et al. Neoadjuvant toripalimab plus platinum-paclitaxel chemotherapy in stage II-III non-small cell lung cancer: a single-center, single-arm, phase I study in China. Invest New Drugs. 2023;41(1):86-92. doi: 10.1007/s10637-022-01324-5. Epub 2022 Dec 12. PMID: 36508040.	2
Zhu X, Sun L, Song N, et al. Safety and effectiveness of neoadjuvant PD-1 inhibitor (toripalimab) plus chemotherapy in stage II-III NSCLC (LungMate 002): an open-label, single-arm, phase 2 trial. BMC Med. 2022;20(1):493. Published 2022 Dec 30. doi: 10.1186/s12916-022-02696-4. PMID: 36581917; PMCID: PMC9801594.	2
Zhao ZR, Yang CP, Chen S, et al. Phase 2 trial of neoadjuvant toripalimab with chemotherapy for resectable stage III non-small-cell lung cancer. Oncoimmunology. 2021;10(1):1996000. Published 2021 Oct 25. doi: 10.1080/2162402X.2021.1996000. PMID: 34712513; PMCID: PMC8547836.	2
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.	1
Jiang T, Wang P, Zhang J, et al. Toripalimab plus chemotherapy as second-line treatment in previously EGFR-TKI treated patients with EGFR-mutant-advanced NSCLC: a multicenter phase-II trial. Signal Transduct Target Ther. 2021;6(1):355. Published 2021 Oct 15. doi: 10.1038/s41392-021-00751-9. PMID: 34650034; PMCID: PMC8517012	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
Todd Gersten	Evidence Favors Efficacy	Class IIa: Recommended, in Most Cases	The addition of toripalimab in this setting improves efficacy end points including RR, EFS, and potentially OS. The limitations in this setting include that the study was predominantly in an Asian population raising questions regarding extrapolation to a Caucasian population	
Jeffrey Klein	Evidence Favors Efficacy	Class IIa: Recommended, in Most Cases	The use of Toripalimab with platinum chemotherapy pre and post surgery NSCLC patients showed an overall increase in overall survival and progression free survival when compared to placebo. Patients in this study were stage 2 or 3 as well as resectable. More adverse effects were seen with the Toripalimab group.	

Warren Brenner	Effective	Class IIa: Recommended, in Most Cases	This was a well conducted large phase III randomized trial asking the question of the benefit of 10 therapy to chemotherapy in patients with locally advanced lung cancer. It is an effective regimen with significant improvement in EFS and pathological CR in patients with stage III disease. It adds further to the current literature showing the effectiveness of 10 therapy in combination with chemotherapy in the neoadjuvant space with impressive HR for EFS and pathological CR rate. I assigned a class IIa recommendation based on Asian only population and almost all patients were male. We also don't know if this is as effective, or more or less effective than current approaches in this space where chemo with Io therapy is already being used.	