

## COMPENDIA TRANSPARENCY TRACKING FORM FOR ONCOLOGY OFF-LABEL USES DERIVED FROM GUIDELINES

**DATE:** February 1, 2025

**DRUG NAME:** Pembrolizumab

**OFF-LABEL USE:** Melanoma, neoadjuvant, resectable, stage III or IV 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, \*to meet requirement 1(C, L, R, S)

CODE	EVALUATION/PRIORITIZATION CRITERIA
A	Treatment represents an established standard of care or significant <b>advance</b> over current therapies
C	<b>Cancer</b> or cancer-related condition
E	Quantity and robustness of <b>evidence</b> for use support consideration
L	<b>Limited</b> alternative therapies exist for condition of interest
P	<b>Pediatric</b> condition
R	<b>Rare</b> disease
S	<b>Serious</b> , 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
----------	-----------------

<p>Amaral T, Ottaviano M, Arance A, Blank C, Chiarion-Sileni V, Donia M, Dummer R, Garbe C, Gershenwald JE, Gogas H, Guckenberger M, Haanen J, Hamid O, Hauschild A, Höller C, Lebbé C, Lee RJ, Long GV, Lorigan P, Muñoz Couselo E, Nathan P, Robert C, Romano E, Schadendorf D, Sondak V, Suijkerbuijk KPM, van Akkooi ACJ, Michielin O, Ascierto PA; ESMO Guidelines Committee. Electronic address: clinicalguidelines@esmo.org. Cutaneous melanoma: ESMO Clinical Practice Guideline for diagnosis, treatment and follow-up. Ann Oncol. 2025 Jan;36(1):10-30. doi: 10.1016/j.annonc.2024.11.006. Epub 2024 Nov 14. PMID: 39550033.</p>	S
<p>Patel SP, Othus M, Chen Y, Wright GP Jr, Yost KJ, Hyngstrom JR, Hu-Lieskovan S, Lao CD, Fecher LA, Truong TG, Eisenstein JL, Chandra S, Sosman JA, Kendra KL, Wu RC, Devoe CE, Deutsch GB, Hegde A, Khalil M, Mangla A, Reese AM, Ross MI, Poklepovic AS, Phan GQ, Onitilo AA, Yasar DG, Powers BC, Doolittle GC, In GK, Kokot N, Gibney GT, Atkins MB, Shaheen M, Warneke JA, Ikeguchi A, Najera JE, Chmielewski B, Crompton JG, Floyd JD, Hsueh E, Margolin KA, Chow WA, Grossmann KF, Dietrich E, Prieto VG, Lowe MC, Buchbinder EI, Kirkwood JM, Korde L, Moon J, Sharon E, Sondak VK, Ribas A. Neoadjuvant-Adjuvant or Adjuvant-Only Pembrolizumab in Advanced Melanoma. N Engl J Med. 2023 Mar 2;388(9):813-823. doi: 10.1056/NEJMoa2211437. PMID: 36856617; PMCID: PMC10410527.S</p>	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
Stacy LaClaire, PharmD	None
Catherine Sabatos, Pharm D	None

### ASSIGNMENT OF RATINGS:

\*to meet requirement 4

	EFFICACY	STRENGTH OF RECOMMENDATION	STRENGTH OF EVIDENCE
MERATIVE MICROMEDEX	Evidence Favors Efficacy	Class IIB	B

