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

DATE: January 1, 2025

DRUG NAME: Nivolumab

OFF-LABEL USE: Melanoma, Neoadjuvant, resectable, stage III disease, in combination with ipilimumab

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 **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

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.	S
Blank CU, Lucas MW, Scolyer RA, van de Wiel BA, Menzies AM, Lopez-Yurda M, Hoeijmakers LL, Saw RPM, Lijnsvelt JM, Maher NG, Pulleman SM, Gonzalez M, Torres Acosta A, van Houdt WJ, Lo SN, Kuijpers AMJ, Spillane A, Klop WMC, Pennington TE, Zuur CL, Shannon KF, Seinstra BA, Rawson RV, Haanen JBAG, Ch'ng S, Naipal KAT, Stretch J, van Thienen JV, Rtshiladze MA, Wilgenhof S, Kapoor R, Meerveld-Eggink A, Grijpink-Ongering LG, van Akkooi ACJ, Reijers ILM, Gyorki DE, Grünhagen DJ, Speetjens FM, Vliek SB, Placzke J, Spain L, Stassen RC, Amini-Adle M, Lebbé C, Faries MB, Robert C, Ascierto PA, van Rijn R, van den Berkmortel FWPJ, Piersma D, van der Westhuizen A, Vreugdenhil G, Aarts MJB, Stevense-den Boer MAM, Atkinson V, Khattak M, Andrews MC, van den Eertwegh AJM, Boers-Sonderen MJ, Hospers GAP, Carlino MS, de Groot JB, Kapiteijn E, Suijkerbuijk KPM, Rutkowski P, Sandhu S, van der Veldt AAM, Long GV. Neoadjuvant Nivolumab and Ipilimumab in Resectable Stage III Melanoma. N Engl J Med. 2024 Nov 7;391(18):1696-1708. doi: 10.1056/NEJMoa2402604. Epub 2024 Jun 2. PMID: 38828984.	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 IIA	B
