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NCCN Guidelines Panel: Hodgkin Lymphoma

Specific changes requested:
On behalf of Merck & Co., Inc., we respectfully request the NCCN Hodgkin lymphoma panel review the enclosed data and consider adding KEYTRUDA® (pembrolizumab) for the treatment of refractory classical Hodgkin lymphoma and for the treatment of cHL patients who have relapsed after 3 or more prior lines of therapy.

FDA Clearance (1):
Melanoma
KEYTRUDA is indicated for the treatment of patients with unresectable or metastatic melanoma.

Non-Small Cell Lung Cancer
KEYTRUDA is indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have high PD-L1 expression [Tumor Proportion Score (TPS) ≥50%)] as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations.

KEYTRUDA is indicated for the treatment of patients with metastatic NSCLC whose tumors express PD-L1 (TPS ≥1%) as determined by an FDA-approved test, with disease progression on or after platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving KEYTRUDA.

Head and Neck Cancer
KEYTRUDA is indicated for the treatment of patients with recurrent or metastatic head and neck squamous cell carcinoma with disease progression on or after platinum-containing chemotherapy.
This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

Classical Hodgkin Lymphoma
KEYTRUDA is indicated for the treatment of adult and pediatric patients with refractory classical Hodgkin lymphoma (cHL), or who have relapsed after 3 or more prior lines of therapy.
This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

Rationale:
Keytruda is now indicated for the treatment of adult and pediatric patients with refractory classical Hodgkin lymphoma regardless of prior line of therapy, or who have relapsed after 3 or more prior lines of therapy. This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.
Please refer to the attached prescribing information for safety and efficacy data from trial 6 (KEYNOTE-87) supporting this indication.

To assist the committee with their review, I have included the following resources:

1. KEYTRUDA (pembrolizumab) prescribing information. Merck & Co., Inc

Thank you for considering this request. Below is my contact information should you need to contact me for additional information.

Sincerely,

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