NCCN Guidelines Panel: Thymomas and Thymic Carcinomas

On behalf of Merck & Co., Inc., I respectfully request the NCCN Thymomas and Thymic Carcinoma Panel to review the enclosed information for KEYTRUDA (pembrolizumab), in reference to NCCN Guidelines V2.2018 for Thymomas and Thymic Carcinomas.

Specific changes requested:

We respectfully request that KEYTRUDA (pembrolizumab) be added as an anti-PD-1 immunotherapy for previously treated patients with recurrent, unresectable or metastatic thymic carcinomas in the NCCN guidelines for Thymomas and Thymic Carcinomas, including the section THYM-C.

FDA Approval:

KEYTRUDA (pembrolizumab) is not approved for the treatment of patients with unresectable or metastatic thymic carcinoma, with the exception of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) thymic carcinoma that has progressed following prior treatment and who have no satisfactory alternative treatment options. 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 KEYTRUDA Prescribing Information for details on the MSI-H cancer indication and other FDA-approved indications.¹

Rationale:

A single-arm phase 2 study of pembrolizumab was conducted in patients with recurrent or metastatic thymic carcinoma who had progressed after at least one line of chemotherapy. Patients received 200 mg of pembrolizumab every 3 weeks for up to 2 years. The primary objective of the study was the proportion of patients who had achieved a response assessed with RECIST v1.1. Forty patients were evaluable and median follow-up was 20 months. The median number of previous therapies was two (1–6). Twenty one (52%) patients had previous thymectomy and 23 (58%) received previous chest radiation. One (3%) of the 40 eligible patients had a complete response and eight (20%) had partial responses, giving an overall response of 22.5% (95% CI 10.8–38.5). Twenty one (53%) patients had stable disease and ten (25%) patients had disease progression. The most common grade 3 or 4 adverse events were increased AST and ALT, five (13%) patients each. Six (15%) patients developed severe autoimmune toxicity, including two (5%) patients with myocarditis. There were 17 deaths at the time of analysis, but no deaths due to toxicity.²
The following resources are submitted to assist the committee with their review:

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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