

August 14, 2017
Maria Rivas, MD, FACP, FACE
Senior Vice President
Global Medical Affairs
Merck & Co., Inc.
2000 Galloping Hill Road, NJ 07033
(908) 740-6346
Maria.Rivas1@merck.com

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 publication and consider amending the guidelines to include KEYTRUDA® (pembrolizumab) for the treatment of refractory classical Hodgkin lymphoma (cHL) and for the treatment of cHL patients who have relapsed after 3 or more prior lines of therapy, without specific requirement for previous treatment with brentuximab vedotin (BV).

FDA Clearance (Classical Hodgkin Lymphoma) (1):

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 was approved by the FDA for the treatment of adult and pediatric patients with refractory cHL, or who have relapsed after 3 or more prior lines of therapy without specific requirement for previous treatment with BV.

Chen et al (2) published safety and efficacy data of KEYNOTE-087 (N=210), a multicenter, single-arm phase 2 study designed to evaluate the efficacy and safety of pembrolizumab in 3 different cohorts of patients with relapsed or refractory (R/R) cHL.

Cohort 3 (n=60) included patients with R/R cHL who failed autologous stem-cell transplantation (ASCT) and were not treated with post-transplantation BV. Patients in this cohort could have received BV as part of primary treatment, as salvage treatment, or could have been BV naïve.

There were 35 BV naïve patients in Cohort 3. The ORR in this patient population was 71.4% (95% CI, 53.7% to 85.4%), which was consistent with the overall study population ORR of 69.0% (95% CI, 62.3% to 75.2%).

Cohort 1 (n=69) included patients with R/R cHL who progressed after ASCT and BV therapy, and cohort 2 (n=81) included patients with R/R cHL who failed salvage chemotherapy and failed BV therapy, and were thus ineligible for ASCT because of chemoresistant disease.

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

1. KEYTRUDA (pembrolizumab) prescribing information. Merck & Co., Inc
2. Chen, et al. Phase II Study of the Efficacy and Safety of Pembrolizumab for Relapsed/Refractory Classic Hodgkin Lymphoma. J Clin Oncol. 2017 Jul 1;35(19):2125-2132.

Thank you for considering this request. Please contact me for any additional information.

Sincerely,

A handwritten signature in dark ink, appearing to read "Maria Rivas", with a stylized, cursive script.

Maria Rivas, MD, FACP, FACE
Senior Vice President
Global Medical Affairs
Merck & Co., Inc.