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Date of Request: March 18, 2020
NCCN Guidelines Panel: Breast Cancer

NCCN Breast Cancer Panel: On behalf of Merck & Co., Inc., I respectfully request the NCCN Breast Cancer Panel to review the enclosed information for KEYTRUDA (pembrolizumab) in combination with chemotherapy, in reference to preoperative treatment for patients with early triple-negative breast cancer.

Specific Changes: We respectfully request that KEYTRUDA (pembrolizumab) in combination with platinum-based chemotherapy be added as a preoperative therapy regimen for patients with early triple-negative breast cancer.

FDA Clearance: KEYTRUDA (pembrolizumab) in combination with platinum-based chemotherapy is not FDA-approved for the preoperative treatment of patients with triple-negative breast cancer.

Rationale: Schmid P et al. published data from KEYNOTE-522, evaluating the combination of pembrolizumab and platinum-based chemotherapy as neoadjuvant therapy in patients with previously untreated Stage II or Stage III triple-negative breast cancer, followed by adjuvant pembrolizumab or placebo after definitive surgery, which included results of the primary endpoints: pathological complete response (95% CI), defined as ypT0/Tis ypN0 at time of definitive surgery, of 64.8% (59.9-69.5) of patients in the pembrolizumab-chemotherapy group and 51.2% (44.1-58.3) of patients in the placebo-chemotherapy group with an estimated treatment difference of 13.6 percentage points (95% CI, 5.4-21.8; $p<0.001$); Kaplan-Meier estimates of event-free survival (EFS) (95% CI) at 18 months were 91.3% (88.8-93.3) in the pembrolizumab-chemotherapy group and 85.3% (80.3-89.1) in the placebo-chemotherapy group; after a median follow-up of 15.5 months (2.7-25), 7.4% of patients in the pembrolizumab-chemotherapy group had an EFS event compared to 11.8% in the placebo-chemotherapy group (HR: 0.63, 95% CI, 0.43-0.93).

The following resources are submitted to assist the committee with their review.

1. Schmid P, Cortes J, Pusztai H, et al. Pembrolizumab for Early Triple-Negative Breast Cancer. N Engl J Med 2020;382(9):810-821.
2. 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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