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Date of Request: May 29th, 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 previously untreated patients with locally recurrent inoperable or metastatic triple-negative breast cancer.

Specific Changes: We respectfully request that KEYTRUDA (pembrolizumab) in combination with chemotherapy be added as a first-line therapy regimen for patients with locally recurrent inoperable or metastatic triple-negative breast cancer to page BINV-Q 1 of 7.

FDA Clearance: KEYTRUDA (pembrolizumab) in combination with chemotherapy is not FDA-approved for the first-line treatment of patients with locally recurrent inoperable or metastatic triple-negative breast cancer.

Rationale: Cortes J et al. presented data from KEYNOTE-355, evaluating the combination of pembrolizumab plus chemotherapy (nab-paclitaxel, paclitaxel, or gemcitabine/carboplatin) versus placebo plus chemotherapy for patients with previously untreated, locally recurrent inoperable or metastatic triple-negative breast cancer. Results were reported for PFS which was one of the dual primary endpoints of the study. In the prespecified subgroup of patients with PD-L1 CPS ≥10, the median PFS was 9.7 months for pembrolizumab-chemotherapy vs 5.6 months for placebo-chemotherapy with an estimated HR of 0.65 (0.49-0.86); p=0.0012. In the prespecified subgroup of patients with PD-L1 CPS ≥1, statistical significance was not met for the median PFS of 7.6 months for pembrolizumab-chemotherapy vs 5.6 months for placebo-chemotherapy with an HR of 0.74 (0.61-0.90); p=0.0014 (p-value boundary 0.00111). Due to the hierarchical testing strategy, statistical significance was not tested in the ITT population with a median PFS of 7.5 months for pembrolizumab-chemotherapy vs 5.6 months for placebo-chemotherapy with an HR of 0.82 (0.69-0.97).

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

1. KEYTRUDA (pembrolizumab) Prescribing Information. Merck & Co., Inc.
2. Cortes J, et al. KEYNOTE-355: Randomized, double-blind, phase III study of pembrolizumab + chemotherapy versus placebo + chemotherapy for previously untreated locally recurrent inoperable or metastatic triple-negative breast cancer. Abstract #1000. Presented at: the American Society of Clinical Oncology (ASCO) 2020 Annual Meeting; May 29-31.

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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