June 12, 2018

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NCCN Guidelines Panel: Cervical Cancer

On behalf of Merck & Co., Inc., I respectfully request the NCCN Cervical Cancers Panel to review the enclosed information for KEYTRUDA (pembrolizumab), in reference to NCCN Guidelines V1.2018 for Cervical Cancer.

Specific changes requested:

Based on FDA approval on June 12, 2018, we respectfully request that KEYTRUDA (pembrolizumab) be added as a systemic therapeutic option for patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express PD-L1 [Combined Positive Score (CPS) ≥1] as determined by an FDA-approved test.

FDA approval:

Cervical Cancer

On June 12, 2018 the FDA approved KEYTRUDA for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express PD-L1 (CPS ≥1), as determined by an FDA approved test.

On May 23, 2017 the FDA approved KEYTRUDA for the treatment of patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient solid tumors (including cervical cancer) that have progressed following prior treatment and who have no satisfactory alternative treatment options.

These indications are approved under accelerated approval based on tumor response rate and durability of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in the confirmatory trials.[1]

Please refer to the KEYTRUDA Prescribing Information for other FDA-approved indications.[1]

Rationale:

In the KEYNOTE-158 study, 98 patients with recurrent or metastatic cervical cancer were enrolled in a single cohort (Cohort E). 77 patients (79%) had tumors that expressed PD-L1 with a combined positive score (CPS) ≥1 and received at least one line of chemotherapy in the metastatic setting. PD-L1 status was determined using the PD-L1 IHC 22C3 pharmDx Kit. The major efficacy outcome measures were ORR according to RECIST 1.1, as assessed by blinded independent central review, and duration of response. At the time of data cutoff, median follow-up duration was 11.7 months (range 0.6 to 22.7 months). ORR was 14.3% (95% CI: 7.4, 24.1) with complete response rate of 2.6% and partial response rate of 11.7%. The median response duration in these patients was not reached (range 4.1 to 18.6+ months), and 91% of these responding patients had a response duration ≥6 months. KEYTRUDA was discontinued due to adverse reactions in 8% of patients. Serious adverse reactions occurred in 39% of patients receiving KEYTRUDA. The most frequent serious adverse reactions reported included anemia (7%), fistula (4.1%), hemorrhage (4.1%), and infections (except UTIs) (4.1%).[1]

The following resource is 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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