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Date of Request: May 6th 2021
NCCN Guidelines Panel: Esophageal/Gastric Cancers

On behalf of Merck & Co., Inc., I respectfully request the NCCN Esophageal/Gastric Cancers Panel to review the enclosed information for KEYTRUDA (pembrolizumab), in reference to NCCN Gastric Cancer Guideline v2.2021.

Specific Changes: We respectfully request the inclusion of pembrolizumab, in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy, as a first-line treatment option for patients with locally advanced unresectable or metastatic HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma under "Preferred Regimens" as a Category 2A recommendation to the NCCN Gastric Cancer Guideline v2.2021 (page GAST-F 3 of 15) based on the FDA approved indication of KEYTRUDA in gastric cancer.

FDA Clearance:

Gastric Cancer

- KEYTRUDA, in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy, is indicated for the first-line treatment of patients with locally advanced unresectable or metastatic HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma.

This indication is 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.

Please refer to the KEYTRUDA (pembrolizumab) prescribing information for other FDA-approved indications.[1]

Rationale: KEYTRUDA in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy is now FDA-approved for the first-line treatment of patients with locally advanced unresectable or metastatic HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma, based on the results from a phase 3, randomized, multicenter, double-blind, placebo-controlled study KEYNOTE-811. [1]

In an interim efficacy analysis, the major outcome measures assessed were Objective Response Rate (ORR) and Duration of Response (DoR) by BICR using RECIST v 1.1 (modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ). At the time of the interim analysis, ORR and DoR were assessed in the first 264 patients randomized. A statistically significant improvement in ORR with durable responses was demonstrated in patients receiving KEYTRUDA in combination with trastuzumab and chemotherapy (74%, 95% CI: 66 – 82) vs. placebo in combination with trastuzumab and chemotherapy (52%, 95% CI: 43 – 61) ($p < 0.0001$).[1] The complete response rate was 11% in the KEYTRUDA arm and 3.1% in the placebo arm. The partial response rate was 63% in the KEYTRUDA arm and 49% in the placebo arm.

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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