Panel Member request to review CheckMate 577 data regarding nivolumab that was presented at the 2020 European Society for Medical Oncology (ESMO) Annual Meeting for inclusion in the NCCN Guidelines.

External Request:
Submission from Bristol Myers Squibb (9/23/20) to review nivolumab clinical data presented at the 2020 European Society for Medical Oncology (ESMO) Annual Meeting and consider:
- the inclusion of nivolumab as a Category 1 treatment option in the adjuvant setting for patients with stage II/III EC/GEJC who complete neoadjuvant chemoradiation therapy followed by surgery (ESOPH-F, page 2 of 15)

Based on the review of the data and discussion, the panel consensus was to include nivolumab as a treatment option in the following pages of the guidelines:

**ESOPH-7** (Squamous Cell Carcinoma)
- Postoperative management for R0 resection (yp T positive and/or N positive) patients who have received preoperative chemoradiation: Nivolumab was added to the guidelines as a category 1 recommendation.

**ESOPH-16** (Adenocarcinoma)
- Postoperative Management for R0 resection (yp T positive and/or N positive) patients who have received chemoradiation. Nivolumab was added to the guidelines as a category 1 recommendation.

**ESOPH-F 2 of 15**
- Preoperative therapy: Nivolumab listed as an option only after preoperative chemoradiation with R0 resection and residual disease. This is a category 1 (preferred) recommendation.

Reference
Panel Member request to review CheckMate 649 data regarding nivolumab that was presented at the 2020 European Society for Medical Oncology (ESMO) Annual Meeting for inclusion in the NCCN Guidelines.

External Request:
Submission from Bristol Myers Squibb (9/23/20) to review nivolumab clinical data presented at the 2020 European Society for Medical Oncology (ESMO) Annual Meeting and consider:

- the inclusion of nivolumab in combination with FOLFOX or CapeOX as a Category 1 treatment option for patients with previously untreated, unresectable, advanced or metastatic GEJC or EAC (ESOPH-F, page 3 of 15).

Based on the review of the data and discussion, the panel consensus was to include “fluoropyrimidine (fluorouracil or capecitabine), oxaliplatin, and nivolumab (PDL1 CPS ≥ 5) for adenocarcinoma” as a first-line treatment option for HER2 overexpression negative unresectable locally advanced, recurrent, or metastatic disease. This is a category 1 (preferred) recommendation.

Reference

Panel Member request to review the KEYNOTE-590 study data regarding pembrolizumab with chemotherapy for inclusion in the Guidelines.

External Request:
Submission from Merck & Co (09/21/20) requesting the inclusion of pembrolizumab, in combination with chemotherapy, as a first-line treatment option for patients with locally advanced unresectable or metastatic esophageal and gastroesophageal junction (GEJ) carcinoma as a Category 1 recommendation.

Based on the review of the data and discussion, the panel consensus was to include the noted systemic therapies as preferred first-line treatment options for HER2 overexpression negative unresectable locally advanced, recurrent, or metastatic disease.

- Fluoropyrimidine (fluorouracil or capecitabine), oxaliplatin, and pembrolizumab (PDL1 CPS ≥ 10)
- Fluoropyrimidine (fluorouracil or capecitabine), cisplatin, and pembrolizumab (PDL1 CPS ≥ 10) (category 1)

Reference
Panel Member request to review the data and category of evidence for ECF and ECF modifications in the Guidelines

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