### Endometrial Carcinoma

**ENDO-A**

External request:
Submission from Foundation Medicine, Inc (06/30/20) requesting to amend Principles of Molecular Analysis section on page ENDO-A 2 of 4 to include TMB testing through a validated and/or FDA-approved assay and add a footnote referencing Merino DM, et al. J Immunother Cancer 2020;8:e000147.

Based on a review of the data, the panel consensus supported the inclusion of the following bullet in the Principles of Molecular Analysis to address the submission:

> Consider TMB testing through a validated and/or FDA-approved assay.

Reference:

**ENDO-D**

External request:
Submission from Merck & Co., Inc. (06/17/20) requesting the inclusion of pembrolizumab as a treatment option for patients with advanced tumor mutational burden-high (TMB-H) endometrial carcinoma who have progressed following prior treatment and have no satisfactory alternative treatment to page ENDO-D (1 of 2).

External request:
Submission from Foundation Medicine, Inc (06/30/20) requesting to add pembrolizumab as a treatment option for patients with unresectable or metastatic tumors with tissue tumor mutational burden-high (TMB-H) ≥10 mutations/megabase, as determined by an FDA-approved test, who have progressed following prior treatment and who have no satisfactory alternative treatment options. (ENDO-D 1 of 2)

Based on the review of the data in the noted reference and the recent FDA approval, the panel consensus was to include pembrolizumab as an option for patients with advanced tumor mutational burden-high (TMB-H) endometrial carcinoma who have progressed following prior treatment and have no satisfactory alternative treatment. This is a category 2A, [useful in certain circumstances] recommendation.

The following corresponding footnote was also added: NCCN recommends TMB-H testing if not previously done. Pembrolizumab is indicated for patients with unresectable or metastatic tumors with TMB-H [≥10 mutations/megabase (mut/Mb)], as determined by an FDA-approved test, who have progressed following prior treatment and who have no satisfactory alternative treatment options.

Reference:
### Uterine Sarcoma

**UTSARC-A**

**External request:**
Submission from Foundation Medicine, Inc (06/30/20) requesting to add a bullet point under “Molecular Analysis for Sarcoma” on page UTSARC-A 1 of 5 that states: *Comprehensive genomic profiling with a validated and/or FDA-approved assay is informative for predicting rare pan-tumor targeted therapy opportunities and should include at least NTRK, MSI, and TMB.*


**Panel Discussion/References**

- Based on a review of the data, the panel consensus supported the addition of the following bullet within the “Molecular Analysis for Sarcoma” section of the Principles of Pathology: *

  > Comprehensive genomic profiling with a validated and/or FDA-approved assay is informative for predicting rare pan-tumor targeted therapy opportunities and should include at least NTRK, MSI, and TMB.

  Reference:

**Institution Vote**

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**UTSARC-C**

**External request:**
Submission from Merck & Co., Inc. (06/17/20) requesting the inclusion of pembrolizumab as a treatment option for patients with advanced tumor mutational burden-high (TMB-H) uterine sarcoma who have progressed following prior treatment and have no satisfactory alternative treatment page ENDO-D (1 of 2).

**Panel Discussion/References**

- Based on the review of the data in the noted reference and the recent FDA approval, the panel consensus was to include pembrolizumab as an option for patients with advanced tumor mutational burden-high (TMB-H) uterine sarcoma who have progressed following prior treatment and have no satisfactory alternative treatment. This is a category 2A, [useful in certain circumstances recommendation.

  The following corresponding footnote was also added: *For the treatment of patients with unresectable or metastatic tumor mutational burden-high (TMB-H) [≥10 mutations/megabase (mut/Mb)] tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options.*

**Institution Vote**

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