Specific Changes:

Modify the BRCA1/2 testing criteria on page BRCA-1 to include both of the following:

1. Expanded criteria for patients with a personal history of pancreatic cancer
   a. Replace bullet points 6 and 7 with “Personal history of pancreatic cancer at any age.”
2. Inclusion of metastatic prostate cancer
   a. Add a separate bullet point after bullet point number 5 stating “Personal history of metastatic prostate cancer at any age.”
   b. Anywhere there is a reference to a family member with prostate cancer (Gleason score ≥7), add “or metastatic prostate cancer”.

FDA Clearance: Not applicable.

Rationale: Multiple recent studies have demonstrated high positive rates for BRCA1/2 in patients with a personal history of pancreatic cancer or metastatic prostate cancer regardless of age and family history. Additionally, while it is unlikely that patients will know the Gleason score for a relative’s prostate cancer, they would likely know whether the relative died of metastatic prostate cancer. This change would allow for more accurate and practical family history assessment relative to prostate cancer diagnoses.

The following articles are submitted in support of this proposed change. We would like to acknowledge the contributions of NCCN panel members who are also co-authors or co-contributors of some of these publications.

Pancreatic cancer references:


Prostate cancer references:


Sincerely,

Johnathan Lancaster, MD, PhD
Chief Medical Officer
Myriad Genetic Laboratories Inc.