

Submitted by: Chief Medical Officer

Name: Johnathan Lancaster, MD, PhD Company/Organization: Myriad Genetic Laboratories, Inc.

Address: 320 Wakara Way, Salt Lake City, UT 84108

Phone: 801-505-5090

Email: jlancaster@myriad.com

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NCCN Guidelines Panel: Genetic/Familial High Risk Assessment: Breast and Ovarian

## Specific Changes:

Update the Criteria for Further Risk Evaluation on page BR/OV-1 so that they are aligned with the *BRCA1/2* Test Criteria found on page BRCA-1 as they are currently narrower than testing criteria. Possible changes are:

Add the following bullet point:

 An individual with an HBOC-related cancer (breast, ovarian, pancreatic or prostate) at any age and a known mutation in a cancer susceptibility gene within the family

Modify the following sub-bullet of the current second bullet point to include a relative with male breast cancer:

- An individual with a breast cancer diagnosis meeting any of the following:
  - ♦ A close relative with male breast cancer

Add the following bullet point:

- An individual with prostate cancer or pancreatic cancer at any age and any of the following:
  - ≥1 relative with ovarian cancer at any age or
  - ≥1 relative with breast cancer ≤50

<u>FDA Clearance</u>: Not applicable.

## Rationale:

Given that the purpose of Criteria for Further Risk Evaluation (page BR/OV-1) is to identify individuals who may benefit from genetic risk assessment/counseling, testing, these criteria should be more inclusive than the explicit criteria for *BRCA1/2* Testing (page BRCA-1). As the

Criteria for Further Risk Evaluation are currently written, there are patients who do not meet the criteria on page BR/OV-1, but who do meet the criteria for genetic testing on page BRCA-1 (i.e., an individual with pancreatic cancer or prostate cancer and a first-degree relative with breast cancer <50).

No references are submitted in support of this request, which pertains solely to the internal consistency of the guideline.

Sincerely,

Johnathan Lancaster, MD, PhD Chief Medical Officer

Myriad Genetic Laboratories Inc.