Submitted by:	Chief Medical Officer
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Date of request:	March 9, 2018
NCCN Guidelines Panel:	Genetic/Familial High Risk Assessment: Breast and Ovarian

Specific Changes:

Add the following bullet (with footnote) to the list of testing criteria on page BRCA-1 acknowledging that individuals who are affected with an HBOC-related cancer can use genetic test results to guide current or future treatment.

- Individuals with a diagnosis of an HBOC-related cancer, i.e., metastatic breast cancer or ovarian cancer who are or may become eligible for treatment with an FDA-approved PARP inhibitor; or individuals with a diagnosis of prostate cancer to determine eligibility for certain therapies and/or clinical trials. Consult the relevant NCCN cancer treatment guideline for details.[a]

[a] The FDA has approved use of certain PARP inhibitors for carriers of germline mutations in *BRCA1* and *BRCA2*, as detected by an FDA-approved test, for metastatic breast cancer (See NCCN Guidelines for Breast Cancer Treatment) and ovarian cancer (See NCCN Guidelines for Ovarian Cancer Treatment). In addition, individuals with prostate cancer who carry germline or somatic mutations in BRCA1, BRCA2, or other genes may be eligible for early use of platinum chemotherapy or clinical trials (e.g. PARP inhibitors) (See NCCN Guidelines for Prostate Cancer Treatment).

FDA Clearance:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/208558s002lbl.pdf

https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/209115s000lbl.pdf

Rationale:

Genetic testing performed for suspicion of hereditary risk utilizes the same CPT codes as testing performed for treatment-related purposes, so it is important to include treatment-related criteria prominently on page BRCA-1 to reduce the likelihood that testing will be delayed or denied for patients who are eligible based on treatment criteria but who do not meet the criteria based on hereditary cancer risk assessment.

The following references are submitted in support of this proposed change:

NCCN Clinical Practice Guidelines in Oncology: Breast Cancer Version 4.2017 (see BINV-O page 1 of 7)

NCCN Clinical Practice Guidelines in Oncology: Ovarian Cancer Version 2.2018 (see OV-B page 5 of 10)

NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer Version 1.2018 (see pages PROS-2 and PROS-3)

Sincerely,

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