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Date of request:	April 1, 2019
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.

- Bullet: Individuals with a diagnosis of breast cancer regardless of age or family history are candidates for germline genetic testing.
- Footnote: Increasing evidence suggests that the identification of pathogenic/likely pathogenic variants may direct use of targeted therapies

FDA Clearance: Not applicable

Rationale:

Recent studies have uniformly demonstrated that the traditional clinical and family history features used to select patients for hereditary cancer testing miss a substantial proportion of germline mutation carriers who could benefit from germline testing to guide the use of targeted therapies and application of risk reduction measures to prevent additional cancers in themselves and their relatives. Simplified testing guidelines, such as those in the American Society of Breast Surgeons Consensus Statement, provide clear and straightforward testing guidance consistent with current knowledge.

The following references support this proposed change:

1. American Society of Breast Surgeons: Consensus Guideline on Genetic Testing for Hereditary Breast Cancer. Available at www.breastsurgeons.org/ about/statements/PDF_Statements/Hereditary_Genetic_Testing_Patients_ With_Without_Breast_Cancer.pdf. Accessed February 18, 2019.
2. Li J et al. Prevalence of BRCA1 and BRCA2 pathogenic variants in a large, unselected breast cancer cohort. *Int J Cancer.* 2019;144(5):1195-1204.
3. Knerr et al. Trends in BRCA Test Utilization in an Integrated Health System, 2005-2015 *J Natl Cancer Inst.* 2019 Feb 8. [Epub ahead of print].

4. Beitsch PD, et al. Underdiagnosis of Hereditary Breast Cancer: Are Genetic Testing Guidelines a Tool or an Obstacle?*J Clin Oncol.* 2019;37(6):453-460.
5. Buchanan et al. Early cancer diagnoses through BRCA1/2 screening of unselected adult biobank participants. Genet Med. 2018 Apr;20(5):554-558.
6. Yang et al. Underdiagnosis of Hereditary Breast and Ovarian Cancer in Medicare Patients: Genetic Testing Criteria Miss the Mark. *Ann Surg Oncol.* 2018 Oct;25(10):2925-2931.

Sincerely,

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