Specific Changes: On page OV-1, replace “refer for genetic risk evaluation” to “perform genetic testing to obtain BRCA status.” Add footnote “In light of the multiple genes associated with ovarian cancer risk, a multi syndrome panel should be considered as an appropriate approach.”

FDA Approval: BRACAnalysis CDx is an FDA-approved companion diagnostic test for germline BRCA1 and BRCA2 mutations intended to be used as an aid in treatment decision making for Lynparza™ (olaparib), a PARP inhibitor.

Rationale: In addition to the familial risk that is identified with genetic testing, several treatment options for ovarian cancer including platinum based therapies, PARP inhibitors, neoadjuvant treatment and intra-peritoneal therapy have been shown to have greater efficacy in patients with BRCA1 and BRCA2 mutations. As a result it is critical that physicians know a patient’s BRCA status at diagnosis to plan treatment.

Multiple studies have demonstrated that multi-syndrome panel testing significantly increases the number of individuals with ovarian cancer identified with clinically significant pathogenic variants. Ovarian cancer risk is associated multiple genes including BRCA1, BRCA2, BRIP1, Lynch syndrome genes, p53, RAD51C and RAD51D.

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.

Treatments benefits in BRCA1 and BRCA2 carriers:


Genes associated with ovarian cancer risk:


Sincerely,

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