Specific Changes:
Change top line of page BRCA-1 from “BRCA1/2 testing criteria” to “BRCA1/2 and PALB2 testing criteria”.

FDA Clearance: Not applicable

Rationale:
With the advent of panel testing, other genes with risk for breast and ovarian cancer are regularly included along with testing of BRCA1/2. PALB2 has been consistently shown to confer a breast cancer risk similar in magnitude to BRCA2. As such, risk reducing mastectomy may be an appropriate intervention for patients with a pathogenic variant in PALB2. When a risk-reducing surgical option is available, the implications to patient management are important enough that, given risks similar to BRCA2, this gene should be highlighted in the testing criteria.

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


Sincerely,

Johnathan Lancaster, MD, PhD
Chief Medical Officer
Myriad Genetics Inc.