Specific Changes: On page PROSD-2, remove the History and Physical bullet point “Family history of BRCA1/2 mutations” and replace the Family history bullet point with “Family history and genetic risk assessment”, adding a footnote: “A family history of prostate cancer increases risk for the disease. In some cases, a personal and/or family history of cancer, including prostate, colorectal, pancreatic, breast, and/or ovarian, may be a sign of an inherited cancer syndrome associated with an increased risk for prostate cancer, i.e. mutations in the genes BRCA1 and BRCA2. Men who meet existing criteria for hereditary cancer risk assessment and testing should be referred appropriately and the results incorporated into the prostate cancer screening risk benefit discussion (see “NCCN Guidelines for Genetic/Familial High-Risk Assessment: Breast and Ovarian, Guidelines for Genetic/Familial High-Risk Assessment: Colorectal”).”

FDA Clearance: Not applicable.

Rationale: The NCCN Guidelines for Genetic/Familial High-Risk Assessment: Breast and Ovarian and Genetic/Familial High-Risk Assessment: Colorectal contain specific criteria for genetic risk assessment and testing of men with a personal and/or family history of prostate and/or other cancers. Recent studies have found that >10% of men with advanced prostate cancer carry inherited mutations in DNA repair genes, highlighting the importance of genetic risk assessment/testing as an essential component of the screening risk benefit discussion.

Citations: 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.


Sincerely,

Michael Brawer, MD
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