On behalf of Exosome Diagnostics, Inc., I respectfully request that the NCCN (Prostate Cancer Early Detection Panel) review the enclosed data for inclusion of the non-invasive (non-DRE), simple urine-based exosome 3-gene expression assay (EoxDx Prostate(IntelliScore) or EPI to further define the probability of high-grade Gleason score 7 prostate cancer on an initial biopsy for men presenting with a PSA 2-10 ng/mL.

Specific Changes: Recommend the EPI non-DRE urine test in patients with PSA levels between 2-10 ng/mL who have not yet had a biopsy.

FDA Clearance: The EPI test is an uncleared and unapproved In Vitro Diagnostic assay and best defined as a Clinical Laboratory Improvement Amendments (CLIA)-certified, Laboratory Derived Test.

Rationale: Overtreatment of clinically insignificant prostate cancer is a concern for early detection protocols. Furthermore, the recent emphasis on the ability to discriminate high grade Gleason 7 prostate cancer from Gleason 6 and benign processes further supports the evidence that only a small percentage of men with low grade Gleason 6 or even low volume Gleason 7 (3+4) disease will progress. Aggregate evidence from recent randomized trials suggests that optimal prostate cancer early detection methods would preferentially identify patients with high grade tumors for biopsy while avoiding biopsy in men without cancer or with low grade disease. It is thought that such an approach would have the potential to maintain mortality reduction while reducing biopsy-associated morbidities and overtreatment of indolent cancer.

The following references are submitted in support of this proposed change. We would like to further acknowledge the contributions of NCCN panel members as co-authors in the published validation study (reference #1 and the upcoming extended validation trials with CarePath – AUA submitted abstracts, reference #3 and 4). We have also included three (confidential) additional abstracts (highlighted in yellow), 2 submitted to the AUA, 2018 and one accepted to ASCO-GU, 2018.


4. McKiernan J, Donovan MJ, Margolis A. et al. Development of a clinical implementation plan (CarePath) for a novel urine exosome gene expression assay as part of a two-cohort, adaptive impact utility trial. SUBMITTED TO AUA, 2018. CONFIDENTIAL


