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Date of request: 06/09/2016
NCCN Guidelines Panel: Prostate Cancer Panel

I respectfully request the *NCCN Prostate Cancer Panel* to review PTEN status as a prognostic biomarker in prostate cancer.

Specific Changes: Recommend tumor PTEN status as a routine component of the diagnostic evaluation of prostate cancer.

FDA Clearance: Testing for PTEN in clinical laboratories does not currently require FDA approval.

Rationale: PTEN is the most frequently altered gene in prostate cancer. Over 20 years of study and publication all point in the same direction. PTEN deleted tumors behave more aggressively than PTEN intact tumors. Recent studies supported by the Canary Foundation validated these findings in a multicenter cohort of over 600 cancers. Both fluorescence in situ hybridization (FISH) and immunohistochemistry (IHC) were applied to the same cohort. For some years, the lack of a good antibody for PTEN inhibited its use in prostate cancer. IHC opens the door to economical testing of this long-studied biomarker.

The following articles are submitted in support of this proposed addition.

Lotan T, Wei W, Ludkovski O, Morais C, Jamaspishvili T, Hawley S, Feng Z, Fazli L, Antonio Hurtado-Coll A, McKenney J, Simko J, Carroll P, Gleave M, Lin D, Nelson PS, Thompson IM, True L, Brooks J, Lance R, Troyer D, Squire J, Guedes L, and Lopez K, Analytic Validation of a Clinical-Grade PTEN Immunohistochemistry Assay in Prostate Cancer by Comparison to PTEN FISH. *Mod Pathol.* 2016 May 13. doi: 10.1038/modpathol.2016.88. [Epub ahead of print]

Troyer DA, Jamaspishvili T, Wei W, Feng Z, Good J, Hawley S, Fazli L, McKenney JK, Simko J, Hurtado-Coll A, Carroll PR, Gleave M, Lane R, Lin DW, Nelson PS, Thompson IM, True LD, Brooks JD, Squire JA. A multicenter study shows PTEN deletion is strongly associated with seminal vesicle involvement and extracapsular extension in localized prostate cancer. *The Prostate* 2015, 75(11):1206-15

Sincerely,

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