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Clinical Benefits and Costs of a 17-gene Assay Designed to Assess Disease-Progression Risk after Positive Prostate Cancer Biopsy

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Introduction and Objectives

Active surveillance (AS) and immediate therapy, including radical prostatectomy or radiation therapy, are options for management of clinically low-risk prostate cancer (PCa). Due to heterogeneity and multifocality, current clinical and pathological measures cannot assess tumor aggressiveness accurately. A 17-gene assay Genomic Prostate Score (GPS) has been validated to improve risk assessment for an individual's PCa based on the tumor's underlying biology. Our objective was to analyze the clinical and economic implications of adding GPS to risk assessment versus clinical and pathological assessment alone.

Methods

We conducted a cohort analysis of GPS from a US societal perspective over 5 years. Our data sources included clinical validity studies that reported rates of disease progression, a clinical practice study on how the assay influenced treatment decisions (n=200), studies reporting treatment costs (from 2007-2012), and 10 contemporary AS series of patient experiences with prostate cancer. The primary analysis endpoints were per-patient changes in treatment modalities, immediate and cumulative costs (2014 US currency), and ratio of changes in costs over changes in survival benefit adjusted for quality of life.

Results

With clinical assessment alone, 44% of patients selected AS following the initial diagnosis, which increased to 70% when adding GPS to clinical assessment. With greater use of AS, immediate treatment costs declined by \$5,743; cumulative 5-year costs declined by \$594. This assumes 5-year cost with AS monitoring of \$4,913 and increased adherence to AS by a relative 23% per year with GPS. GPS is cost neutral if the probability of AS patients progressing to definitive treatment declines by at least a relative 10% per year with utilization of the assay. Lower costs were realized for all clinically assessed NCCN risk categories. The most sensitive inputs were initial and deferred costs of definitive treatment.

Conclusions

Incorporating GPS into treatment decisions resulted in greater use of AS, and can reduce overall healthcare costs within 5 years. These findings should assist professional societies to further evaluate both the clinical and the economic impact of genomic tests in treatment decisions.

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