Medical Coverage Policy | Prostate Cancer Genomic Assays

EFFECTIVE DATE: 10|15|2015
POLICY LAST UPDATED: 10|20|2015

OVERVIEW

Prolaris® prostate cancer assay, developed by Myriad, Salt Lake City, UT, and Oncotype DX® Prostate Cancer Assay (Genomic Health™) are used to help determine which patients with early stage, needle biopsy-proven prostate cancer, can be conservatively managed rather than treated with definitive surgery or radiation therapy.

MEDICAL CRITERIA

BlueCHiP for Medicare

The Prolaris and Oncotype DX prostate cancer assays are covered only when the following clinical conditions are met:

- Needle biopsy with localized adenocarcinoma of prostate (no clinical evidence of metastasis or lymph node involvement), **and**
- Patient stage as defined by the one of the following:
  - Very low-risk disease (T1c **AND** Gleason Score ≤ 6 **AND** PSA ≤ 10 ng/mL **AND** <3 prostate cores with tumor **AND** ≤ 50% cancer in any core **AND** PSA density of < 0.15 ng/mL/g) **OR**
  - Low Risk Disease (T1-T2a **AND** Gleason Score ≤ 6 **AND** PSA ≤ 10 ng/mL), **and**
- Patient has an estimated life expectancy of greater than or equal to 10 years, **and**
- Patient is a candidate for and is considering conservative therapy and yet would be eligible for definitive therapy (radical prostectomy, radiation therapy, or brachytherapy), **and**
- Patient has not received pelvic radiation or androgen deprivation therapy prior to the biopsy, **and**
- Test is ordered by a physician certified in a specific Certification and Training Registry (CTR)
  - For Prolaris, ordering physician must be certified in the Myriad Prolaris™ Certification and Training Registry (CTR)
  - For Oncotype DX, ordering physician must be certified in the Genomic Health™ Oncotype DX Prostate Cancer Assay Certification and Training Registry (CTR)

Commercial Products

Not applicable

PRIOR AUTHORIZATION

BlueCHiP for Medicare and Commercial Products

Prior authorization is required for BlueCHiP for Medicare and recommended for Commercial products and is obtained via the online tool for participating providers. See the Related Policies section.

POLICY STATEMENT

BlueCHiP for Medicare

The Prolaris and Oncotype DX prostate cancer assays will be considered medically necessary when the medical criteria listed above are met.

Commercial Products

Gene expression analysis and protein biomarker to guide management of prostate cancer are considered not medically necessary because direct evidence is insufficient to establish the analytical and clinical validity, or the clinical utility of the services.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for limitations of benefits/coverage for laboratory tests or when services are not medically necessary.

BACKGROUND

American Urological Association guidelines suggest patients with low- and intermediate-risk disease have the option of "active surveillance," taking into account patient age, patient preferences, and health conditions related to urinary, sexual, and bowel function. With this approach the patient will forgo immediate therapy and continue regular monitoring until signs or symptoms of disease progression are evident, at which point curative treatment is instituted.

Given the unpredictable behavior of early prostate cancer, additional prognostic methods to biologically stratify this disease are under investigation. These include gene expression profiling, which refers to analysis of mRNA expression levels of many genes simultaneously in a tumor specimen, and protein biomarkers.

Gene expression profile analysis and protein biomarkers have been proposed as a means to risk-stratify patients with prostate cancer to guide treatment decisions. These tests are intended to be used either on prostate needle biopsy tissue to guide management decisions regarding active surveillance versus therapeutic intervention, or after radical prostatectomy (RP) to guide radiotherapy use.

Two gene expression analysis tests, Prolaris and Oncotype Dx Prostate, are intended to be used in combination with accepted clinical criteria (Gleason score, prostate-specific antigen [PSA], clinical stage) to stratify needle biopsy-diagnosed localized prostate cancer according to biological aggressiveness, and direct initial patient management.

Prolaris is an RNA-based assay measuring the expression of 31 cell cycle progression (CCP) genes and 15 "housekeeping" genes that act as internal controls and normalization standards in each patient sample. The assay is performed on formalin fixed paraffin-embedded (FFPE) prostate cancer blocks. The assay results are reported as a numerical score along with accompanying interpretive information.

Oncotype DX Prostate Cancer Assay is prostate biopsy-based 17-gene RT-PCR assay, representing four molecular pathways (androgen signaling, cellular organization, stromal response and proliferation), that provides a biologic measure of cancer aggressiveness. The assay is indicated for men who are considered candidates for active surveillance (AS) (those with NCCN® very low- and low-risk prostate cancer). The assay is designed to inform decisions between AS and immediate treatment.

Many men do not need treatment for their prostate cancer in as much as their prognosis is excellent even without treatment. However, physicians and patients struggle to know who can safely be observed versus the subgroup that needs more aggressive treatment to achieve cure, and recognize that definitive treatment for localized prostate cancer can have lifelong morbidities.

BlueCHiP for Medicare

The Prolaris cell cycle progression (CCP) score was found to be an independent and more robust prognostic factor for disease-related death than traditional clinicopathologic factors although disease stage and Gleason score consistently portended a more negative prognostic picture. The potential usefulness of the Prolaris CCP test is that it allows physicians to determine which patients with early prostate cancer are candidates for active surveillance or observation and are more likely to have a good outcome without needing to receive definitive treatment.

The potential usefulness of the Oncotype DX prostate cancer assay is that it allows physicians to determine which patients with early prostate cancer are candidates for active surveillance and are more likely to have a good outcome without needing to receive definitive treatment.

Commercial Products
Direct evidence is insufficient to establish the analytic validity, clinical validity, or clinical utility of Prolaris and the clinical validity or clinical utility of Oncotype Dx Prostate.

CODING

BlueCHiP for Medicare and Commercial Products
There is not a specific CPT code for this testing. Therefore, the unlisted molecular pathology procedure code 81479 should be used.

The following CPT code requires prior authorization.
81479

RELATED POLICIES

Preauthorization via Web-Based Tool for Genetic Testing

PUBLISHED

Provider Update, December 2015

REFERENCES

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