Gene Expression Profile Analysis for Prostate Cancer Management

DESCRIPTION

Gene expression profile analysis is proposed as a means to risk-stratify individuals with prostate cancer to guide treatment decisions. These tests are intended to be used either on prostate needle-biopsy tissue to guide management regarding active surveillance versus therapeutic intervention, or after radical prostatectomy to guide radiotherapy decisions. Examples of array-based gene expression profiling tests now offered commercially are the Prolaris® (Myriad Genetics), the Oncotype Dx® Prostate Cancer Assay (Genomic Health), Decipher® Prostate Cancer Classifier (Decipher Biosciences, formerly GenomeDX Biosciences), and ProMark Protein Biomarker test (Metamark Genetics).

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 sample. The assay is performed on formalin fixed paraffin-embedded prostate cancer blocks. The assay results are reported as a numerical score along with accompanying interpretive information.

The Oncotype DX Prostate assay includes 5 reference genes and 12 cancer genes that represent 4 molecular pathways of prostate cancer oncogenesis: androgen receptor, cellular organization, stromal response, and proliferation. The assay results are combined to produce a Genomic Prostate Score (GPS), which ranges from 0 to 100. Higher GPS scores indicate more risk.

Decipher Prostate is an mRNA microarray gene expression profiling of 22 content genes, utilizing formalin-fixed paraffin-embedded tissue. Algorithm is reported as metastasis risk score.

The ProMark assay includes eight biomarkers that predict prostate pathology aggressiveness and lethal outcomes: DERL1, PDSS2, pS6, YBX1, HSPA9, FUS, SMAD4, and CUL2. The assay results are combined using predefined coefficients for each marker from a logistic regression model to calculate a risk score.

POLICY

- Gene expression profile analysis to guide the management of prostate cancer is considered **medically necessary** if the medical appropriateness criteria are met. (See Medical Appropriateness below.)

- Gene expression profile analysis for the evaluation of prostate cancer that does not meet medical appropriateness is considered **investigational**.

MEDICAL APPROPRIATENESS

- Gene expression profile analysis to guide the management of prostate cancer is considered **medically appropriate** if ANY ONE of the following are met:
  - Individual with low-or favorable intermediate-risk disease with life expectancy of at least 10 years (e.g., Decipher, Oncotype DX Prostate, Prolaris, and ProMark)
  - Individual with unfavorable intermediate or high-risk disease and life expectancy of at least 10 years (i.e., Decipher or Prolaris tumor-based molecular assays)
  - Individual with high risk disease when adverse pathology is found post radical prostatectomy (i.e., Decipher molecular assay).
IMPORTANT REMINDERS

- Any specific products referenced in this policy are just examples and are intended for illustrative purposes only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available. These examples are contained in the parenthetical e.g. statement.

- We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member’s health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

SOURCES


This document has been classified as public information.
Approved Revised Policy: Do Not Implement Until 7/31/20


Moschini, M., Spahn, M., Mattei, A., Cheville, J., & Karnes, J. (2016). Incorporation of tissue-based genomic biomarkers into localized prostate cancer clinics. BMC Medicine, 14, 67. (Level 2 evidence)


EFFECTIVE DATE 7/31/2020

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