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The Department of Vermont Health Access Clinical Criteria

Subject: Prostate Cancer Genomic Assay
Last Review: September 7, 2023*
Past Revisions: June 13, 2022**,** December 1, 2018

***Please note: Most current content changes will be highlighted in yellow.**

Description of Service or Procedure

Prostate cancer genomic assays are tests that examine prostate cancer cells obtained from needle-biopsy or radical prostatectomy procedures to identify gene alterations that can provide information to aid risk stratification and guidance of treatment decisions. Several different tests are available and should be selected by a knowledgeable provider based on risk of disease, life expectancy, and other clinical considerations. These tests include the following:

- Decipher® is a 22 gene genomic assay, performed on prostate cancer tumor tissue from diagnostic needle-biopsy. The Decipher® test aids to risk stratify patients and provide information related to 5- and 10-year metastatic disease risk.
- OncotypeDX® is a 17 gene genomic assay, performed on prostate cancer tumor tissue from diagnostic needle-biopsy. From the results of the test, a risk score is assigned which correlates with tumor aggressiveness and aids to guide treatment decisions.
- Prolaris® is a 46 gene genomic assay that measures tumor cell growth. It is performed on prostate cancer tumor tissue from diagnostic needle-biopsy. The test results are used in conjunction with other clinical information to risk stratify and guide treatment decisions.

Disclaimer

Coverage is limited to that outlined in Medicaid Rule or Health Care Administrative Rules that pertains to the member's aid category. Prior Authorization (PA) is only valid if the member is eligible for the applicable item or service on the date of service.

Medicaid Rule

Medicaid and Health Care Administrative Rules can be found at https://humanservices.vermont.gov/rules-policies/health-care-rules/health-care-administrative-rules-hcar/adopted-rules

7102.2 Prior Authorization Determination

7405 Laboratory and Radiology Services
4.101 Medical Necessity for Covered Services
4.104 Medicaid Non-Covered Services
4.106 Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Services

Coverage Position

Prostate Cancer Genomic assay tests may be covered for members:

- When the device is prescribed by a licensed medical provider, enrolled in the Vermont Medicaid program, operating within their scope of practice as described on the Vermont Office of Professional Regulation's website*, Statute, or rule who is knowledgeable regarding genetic assays and who provides medical care to the member AND
- When the clinical criteria below are met.

* Vermont's Office of Professional Regulation's website: https://sos.vermont.gov/opr/

Coverage Criteria

DVHA covers testing for prostate cancer genomic assays in alignment with the National Comprehensive Cancer Network (NCCN) guidelines for treatment of prostate cancer. Prior authorization is required for prostate cancer genomic assays. These include Prolaris®, Decipher®, and OncotypeDX®. These tests are utilized to determine risk related to disease progression and the results are used to guide treatment.

Decipher® molecular assay should be considered if not previously performed to inform adjuvant treatment if adverse features are found post radical prostatectomy.

Per the NCCN prostate cancer guideline, patients with NCCN risk groups low, favorable intermediate, unfavorable intermediate, or high-risk disease and life expectancy ≥10 years may consider the use of tumor-based molecular assays including Decipher®, Oncotype DX® Prostate, and Prolaris® during the initial risk stratification process. Additionally, patients with NCCN risk groups of unfavorable intermediate- and high-risk disease and life expectancy greater than or equal to 10 years may consider the use of Decipher® or Prolaris® tests (NCCN Guidelines Version 3.2023 Prostate Cancer, 2023, p. 84).

The NCCN prostate cancer guideline recommendations regarding intended use for these tests is as follows:

> Although full assessment of their clinical utility requires prospective randomized clinical trials, which are unlikely to be done, the panel believes that patients with low or favorable intermediate disease and life expectancy greater than or equal to 10 years may consider the use of Decipher, Oncotype DX Prostate, or Prolaris during initial risk stratification. Patients with unfavorable intermediate- and high-risk disease and life expectancy greater than or equal to 10 years may consider the use of Decipher or Prolaris. In addition, Decipher may be considered to inform adjuvant treatment if adverse features are found after radical prostatectomy and during workup for radical prostatectomy, PSA persistence or recurrence (NCCN Guidelines Version 3.2023 Prostate Cancer, 2023, p. 84).

Further, the NCCN prostate cancer guideline identifies that the Centers for Medicare and Medicaid (CMS) Molecular Diagnostic Services Program (MolDX) recommend coverage for each test as follows (with note of discussion and update in progress) (NCCN Guidelines Version 3.2023 Prostate Cancer,

2023, p. 145):

- Decipher® - post-biopsy for NCCN very-low-, low-risk, favorable intermediate, and unfavorable intermediate risk prostate cancer in patients with at least 10 years life expectancy who have not received treatment for prostate cancer and are candidates for active surveillance or definitive therapy; or
    - Post-radical prostatectomy for 1) pT2 with positive margins; 2) any pT3 disease; 3) rising PSA (above nadir)
- Prolaris® - post-biopsy for NCCN very-low-, low-risk, and favorable intermediate-risk prostate cancer in patients with at least 10 years life expectancy who have not received treatment for prostate cancer and are candidates for active surveillance or definitive therapy.
- OncotypeDx® Prostate – post-biopsy for NCCN very-low-, low-risk, and favorable intermediate-risk prostate cancer in patients with at least 10 years life expectancy who have not received treatment for prostate cancer and are candidates for active surveillance or definitive therapy .

NCCN Guidelines for Prostate Cancer can be found at:
https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf

Considerations: Providers requesting this test should provide pre- and post-test genetic counseling for the member and family, if applicable.

Early and Periodic Screening, Diagnostic and Treatment (EPSDT): Vermont Medicaid will provide comprehensive services and furnish all Medicaid coverable, appropriate, and medically necessary services needed to correct and ameliorate health conditions for Medicaid members under age 21.

Please note, Vermont Medicaid Clinical Criteria is reviewed based on available literature, evidence- based guidelines/standards, Medicaid rule and policy, and Medicare coverage determinations that may be appropriate to incorporate when applicable.

Clinical guidelines for repeat service or procedure

Repeat tests may be needed if tissue sample is determined to be inadequate.

Type of service or procedure covered

- Prolaris®
- Oncotype DX®
- Decipher®

Type of service or procedure not covered (this list may not be all inclusive)

- Ki-67 not recommended by NCCN
- PTEN not recommended by NCCN
- Promark - this test is considered investigational and/or experimental.

Coding guidelines

Please see the Medicaid Portal at http://vtmedicaid.com/#/feeSchedule for fee schedules, code coverage, and applicable requirements.

References

Centers for Medicare and Medicaid Services. (n.d.). *Early and periodic screening, diagnostic, and treatment.* https://www.medicaid.gov/medicaid/benefits/epsdt/index.html

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