The Department of Vermont Health Access Medical Policy

Subject: Prostate Cancer Genomic Assay

Last Review: 12/01/2018
Past Revisions: 12/01/2018

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

Description of Service or Procedure

Prolaris test is a biopsy-based prostate cancer prognostic test. The assay results are reported as a numerical score along with accompanying interpretive information.

Promark Risk Score is a biopsy-based prostate cancer prognostic test.

OncotypeDX: Genomic Prostate Score test is covered for men with favorable intermediate risk prostate cancer only when the following clinical conditions are met per Medicare Guidelines

Decipher is used after a radical prostatectomy to predict the probability of metastasis within 5 years, and thus inform clinical decisions on the potential use of additional (adjuvant) prostate cancer treatments.

Disclaimer

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

Medicaid Rule


7102.2 Prior Authorization Determination
7103 Medical Necessity

Coverage Position

Prostate cancer Genomic assay tests may be covered for beneficiaries:

- When the device is prescribed by a licensed medical provider, enrolled in the Vermont Medicaid program, operating within their scope of practice as described in their Vermont State Practice Act,
Statute, or rule who is knowledgeable regarding genetic assays and who provides medical care to the beneficiary AND

- When the clinical criteria below are met.

**Coverage Criteria**

Prior authorization is required for all Prostate Cancer Genomic Assay’s. These include Prolaris Low Risk, Prolaris Intermediate Risk, Promark, OncotypeDX. Oncotype DX Intermediate Risk and Decipher.

Please follow Medicare guidelines as outlined in the links below.


Local Coverage Determination (LCD): MolDX: Prolaris™ Prostate Cancer Genomic Assay for Men with Favorable Intermediate Risk Disease (L37082)

Local Coverage Determination (LCD): MolDX-CDD: ProMark Risk Score (L36706)

Local Coverage Determination (LCD): MolDX-CDD: Genomic Health™ Oncotype DX® Prostate Cancer Assay (L36368)
https://med.noridianmedicare.com/documents/10546/6990983/MolDX+Decipher+Prostate+Cancer+Classifier+Assay+LCD/0f609902-ae48-4d5c-a5be-f9da3e5907bc

Local Coverage Determination (LCD): MolDX: Oncotype DX® Genomic Prostate Score for Men with Favorable Intermediate Risk Prostate Cancer (L37321).
https://med.noridianmedicare.com/documents/10546/6990983/MolDX+Oncotype+DX+Genomic+Prostate+Score+for+Men+with+Favorable+Intermediate+Risk+Prostate+Cancer+LCD

Local Coverage Determination (LCD): MolDX: Decipher® Prostate Cancer Classifier Assay (L36345)
https://med.noridianmedicare.com/documents/10546/6990983/MolDX+Decipher+Prostate+Cancer+Classifier+Assay+LCD/0f609902-ae48-4d5c-a5be-f9da3e5907bc

**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
- Promark
- Oncotype DX Prostate biopsy
- 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

Coding Guidelines

- Prolaris 81541
- Promark 81479 Unlisted
- OncotypeDX- 81519
- Decipher 81479 Unlisted

References


Local Coverage Determination (LCD): MolDX: Decipher® Prostate Cancer Classifier Assay (L36345). Retrieved on September 2, 2018 from:
https://med.noridianmedicare.com/documents/10546/6990983/MolDX+Decipher+Prostate+Cancer+Classifier+Assay+LCD/0f609902-ae48-4d5c-a5be-f9da3e5907bc

Local Coverage Determination (LCD): MolDX: Oncotype DX® Genomic Prostate Score for Men with Favorable Intermediate Risk Prostate Cancer (L37321). Retrieved on September 2, 2018 from:
https://med.noridianmedicare.com/documents/10546/6990983/MolDX+Oncotype+DX+Genomic+Prostate+Score+for+Men+with+Favorable+Intermediate+Risk+Prostate+Cancer+LCD

Local Coverage Determination (LCD): MolDX: Prolaris™ Prostate Cancer Genomic Assay (L36350). Retrieved on September 2, 2018 from:

Local Coverage Determination (LCD): MolDX: Prolaris™ Prostate Cancer Genomic Assay for Men with Favorable Intermediate Risk Disease (L37082). Retrieved on September 2, 2018 from:


https://www.uptodate.com/contents/molecular-prognostic-tests-for-prostate-cancer/print?search=prolaris&source=search_result&selectedTitle=1~2&usage_type=default&display_rank=1

This document has been classified as public information.