Program Guide
Onco
type
DX® Prostate Cancer Assay Certification and Training Registry (Onco
type
DX CTR)

The Program Guide provides a step-by-step overview of the operational aspects of the Onco
type
DX CTR, including how to:

1. Enroll as a healthcare provider so that you can obtain coverage for your Medicare patients;
2. Order the Onco
type
DX Prostate Cancer Assay for Medicare patients in compliance with Medicare requirements, and
3. Counsel and appropriately monitor your Medicare patients who have received Onco
type
DX Prostate Cancer Assay testing.

The goals of the Genomic Health Onco
type
DX Prostate Cancer Assay CTR program are as follows:

• To ensure that physicians understand the limitations and attributes of the test based on its validation
• To inform prescribers and patients on the safe-use conditions for Onco
type
DX Prostate Cancer Assay
• Make a good faith effort to identify any safety concerns from the use of the test, and
• Facilitate understanding of the incremental clinical utility of the test as an adjunct to the NCCN® guidelines.

Onco
type
DX CTR Materials:

A. Program Guide Pages 1-2
B. Training Package Pages 3-7
C. Healthcare Provider Enrollment (Form 1) Page 8
D. Clinical Criteria Form for Medicare (Form 2) Pages 9-10
E. Adverse Event Report (Form 3) Page 11
F. Patient Guide Page 12
G. www.OncotypeDXctr.com

As the sponsor of Onco
type
DX CTR, Genomic Health has committed to working with healthcare providers to ensure compliance with the registry requirements and to assist in gathering and reporting relevant data to the MolDX program within Palmetto GBA.
1. Provider Enrollment
   a) Carefully review all Oncotype DX Prostate Cancer Assay CTR program documents.
   c) Sign Healthcare Provider Enrollment (Form 1).
   d) If you opt out of using an electronic signature within OncotypeDXctr.com please print, sign and fax (Form 1) to Genomic Health at 650-362-6487.

2. Oncotype DX Prostate Cancer Assay Testing
   a) Test results should be appropriately explained to the patient.
   b) Patients should be counseled on:
      (i) the benefits and risks of the Oncotype DX Prostate Cancer assay test, and
      (ii) the need for continued, appropriate monitoring.
   c) Schedule and document in patient’s medical record appropriate follow-up visits, tests and procedures for Medicare patients tested under Oncotype DX CTR.

3. Data Reporting
   a) For patients who were deemed Very-Low or Low risk by the assay and did not receive treatment, the provider should report:
      • Prostate Cancer Progression
      • Prostate Cancer Metastasis
      • Prostate Cancer Specific Mortality
   b) Complete the Adverse Event Report (Form 3) and submit it to Genomic Health.

4. Program Compliance
   a) The LCD requires registered healthcare providers to comply with all obligations of the Oncotype DX Prostate Cancer Assay CTR in order to maintain their certification.
   b) As sponsor of the Oncotype DX Prostate Cancer Assay CTR, Genomic Health may contact you from time-to-time to assist you with your continued compliance with the Oncotype DX Prostate Cancer Assay CTR.
   c) In the event of a continued failure to remain in compliance with the terms of the LCD and the Oncotype DX Prostate Cancer Assay CTR, Genomic Health is charged with taking appropriate measures to bring registered healthcare providers into compliance, including by instituting corrective actions up to and including de-certification.
The Onco type DX Prostate Cancer Assay Certification and Training Registry (CTR) has been established to enable Medicare coverage for testing of patients. Under Local Coverage Determination (LCD) L36153 effective October 13th 2015, the Onco type DX Prostate Cancer Assay is considered “reasonable and necessary” for Medicare patients meeting identified coverage criteria.

1. **Oncotype DX Prostate Cancer Assay Overview**

The Oncotype DX Prostate Cancer Assay (Genomic Health, Inc., Redwood City, CA), is a commercially available biopsy-based RT-PCR assay that reports a Genomic Prostate Score (GPS, range from 0-100). The assay is indicated for men with Very-Low, Low and Intermediate risk prostate cancer. When used in combination with traditional clinical risk assessment tools, the assay provides a more precise estimate of whether the patient has indolent or aggressive disease. The GPS should be used in the context of NCCN® clinical risk groups and can refine risk estimates from conventional clinical population based risk groupings to yield a precise and personalized risk assessment. Precise risk estimation is intended to enhance both the healthcare provider and patient’s ability to make informed decisions about immediate treatment versus active surveillance for prostate cancer.

The Oncotype DX Prostate Cancer Assay is a multi-gene quantitative RT-PCR test that analyzes 17 genes (12 cancer–related and 5 reference genes) across four biologic pathways. The assay was clinically validated in men with newly diagnosed clinically low risk prostate cancer with NCCN Very-Low, Low and Intermediate risk criteria. LCD (L36153) provides coverage for patients identified as NCCN Very-Low or Low risk by clinical criteria alone. The GPS measures individual tumor biology to help distinguish clinically indolent versus aggressive prostate cancer. The GPS reports a quantitative score ranging from 0-100 and the associated risks of pathological upstaging and upgrading. A lower GPS is associated with less aggressive disease and a higher GPS with more aggressive disease. Combined with conventional clinical risk assessment, this information provides a more accurate assessment of risk and allows patients newly diagnosed with clinically low-risk prostate cancer to more confidently choose between active surveillance and therapy as their initial management strategy. By adding independent molecular information to established risk parameters, the GPS improves risk stratification at time of diagnosis and helps optimize decisions regarding management of clinically low risk prostate cancer.

2. **Indications for Use**

The Oncotype DX Prostate Cancer Assay is indicated for men diagnosed with NCCN Very-Low, Low and Intermediate risk prostate cancer who are candidates for active surveillance. Only intermediate risk patients who are considered potential candidates for active surveillance are considered appropriate for the assay (see characteristics below).

The NCCN guidelines describe several primary treatment options for clinically low risk prostate cancer patients. The choice of appropriate primary treatment for each patient should be informed by the patient’s life expectancy and an assessment of that patient’s risk of recurrence. Recurrence risk staging systems are recommended by the NCCN guidelines. Risk staging evaluation is based on clinicopathologic patient characteristics, such as tumor size, Gleason score, PSA levels, number of positive biopsy cores, proportion of cancer tissue in biopsy cores, and PSA density. The revised NCCN guidelines now recognize tissue based molecular assays as an option to improve risk stratification for men with localized prostate cancer who have >5 years of life expectancy.*

* NCCN Clinical Practice Guidelines in Oncology®; Prostate Cancer v1. 2015, page 10, footnote b.

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National Comprehensive Cancer Network (NCCN) is a trademark of NCCN. NCCN guidelines do not endorse any product or therapy.
Table 1: NCCN®-Based Risk Categories

<table>
<thead>
<tr>
<th>Very Low</th>
<th>Low</th>
<th>Intermediate</th>
</tr>
</thead>
<tbody>
<tr>
<td>• T1c</td>
<td>• T1-T2a</td>
<td>• T2b-T2c or</td>
</tr>
<tr>
<td>• Gleason score ≤6</td>
<td>• Gleason score ≤6</td>
<td>• Gleason score 7 or</td>
</tr>
<tr>
<td>• PSA &lt;10ng/mL</td>
<td>• PSA &lt;10 ng/mL</td>
<td>• PSA 10–20 ng/mL</td>
</tr>
<tr>
<td>• Fewer than 3 prostate biopsy cores positive, ≤50% cancer in each core</td>
<td>• PSA density &lt;0.15 ng/mL/g</td>
<td></td>
</tr>
</tbody>
</table>

• LCD (L36153) provides coverage for patients identified as NCCN Very-Low or Low risk by clinical criteria alone

3. Patient Management

The Oncotype DX® Prostate Cancer Assay provides a Genomic Prostate Score (GPS) which is used with NCCN risk group to calculate the likelihood of favorable pathology (LFP, defined as Gleason 3+3=6 or 3+4=7 and organ confined) and a 95% CI.

The report incorporates a bar graph that provides NCCN clinical risk and biological risk after including the GPS. Estimated likelihood of freedom from high-grade disease and associated 95% confidence intervals and the freedom from non-organ-confined disease and associated 95% confidence intervals are reported separately on the patient report.

The NCCN very low risk group is defined in the patient report on the bar graph as a likelihood of favorable pathology ≥79%. The NCCN low risk group is defined on the bar graph as a likelihood of favorable pathology between 68-78%. The NCCN intermediate risk group is defined on the bar graph as a likelihood of favorable pathology ≤67%. The cut points establishing the range of likelihood of favorable pathology for the NCCN risk groups were determined from multivariable modeling, including GPS and NCCN risk groups, where 90% of NCCN very low risk patients were observed to have ≥79% chance of favorable pathology and 90% of NCCN intermediate risk patients were observed to have ≤67% chance of favorable pathology. The clinical relevance of these cut points can be simplified as 4 out of 5 patients deemed to have very-low risk prostate cancer by NCCN+GPS will have favorable pathology at time of prostatectomy whereas no more than 2 out of 3 patients with intermediate risk cancer will have favorable pathology.

The Oncotype DX Prostate Cancer Assay test results should be interpreted in conjunction with NCCN guidelines and other laboratory and clinical data available to the clinician.

Safe Use

When used in conjunction with clinical parameters as detailed in section 1 above, the Oncotype DX Prostate Cancer Assay provides additional information beyond clinical and pathological features to aid in the decision making process. Regardless of management selection, prostate cancer patients should be followed by their provider as detailed in relevant guidelines. (e.g., NCCN).

Genomic Health has provided Patient information brochures for you to review with your patients. Please contact your regional urologic specialist (RUL) or customer service at 1-877-662-6897 to reorder these as necessary.
4. Scientific Evidence - Oncotype DX® Prostate Cancer Assay

The development of the Oncotype DX assay included over 1,000 patients and showed the following results:

1. Gene expression can be measured in small amounts of RNA obtained from fixed formalin-embedded (FPE) needle biopsy specimens. On average, 30-50 ng of RNA can be extracted from diagnostic biopsies containing 1 mm of tumor.1,2

2. A initial, exploratory panel of 81 genes predicted the risk of clinical recurrence (CR), biochemical recurrence (BCR), and prostate cancer specific mortality in both primary and highest Gleason pattern samples.4,5

3. A subset of 58 genes predicted high grade and/or non-organ-confined disease in both needle biopsy and prostatectomy samples.6

4. A final 12 cancer-related prognostic genes and 5 reference genes were selected for the final clinical-grade assay (Figure 1). Selection was based on consistency across studies, representation of the four key pathways, and analytical performance (including reproducibility and higher mean expression with wide dynamic range). Strength of association with clinical recurrence was given preferential weighting for gene selection and algorithm development.6

Figure 1. Genes comprising the Oncotype DX® Genomic Prostate Score Assay

There are four key features of the final assay: (1) predicted clinical recurrence (local recurrence and/or metastatic disease) and other endpoints of aggressive prostate cancer, (2) predicted aggressive prostate cancer in the face of tumor heterogeneity and multifocality, (3) higher expression of the stromal response and proliferation genes was associated with more aggressive prostate cancer, (4) higher expression of cellular organization and androgen genes was associated with more favorable prostate cancer.

Analytic Validation

The resulting assay uses an optimized technology platform that reliably provides genomic information about prostate tumor aggressiveness, using quantitative RT-PCR in very small amounts of prostate needle biopsy tissue obtained at diagnosis. The Oncotype DX Prostate Cancer Assay is a laboratory-developed test (LDT) performed only in Genomic Health’s CLIA-certified (Clinical Laboratory Improvement Amendments), CAP-accredited (College of American Pathologists) certified laboratory.

Knezevic et al. analyzed 46 and 167 prostate-biopsy samples from two separate studies to assess the following measures of analytical performance and validity: linearity, amplification efficiency, sensitivity, precision, and reproducibility.7 Average amplification efficiency of the 12 tumor-specific genes and 5 reference genes in the Oncotype DX Prostate Cancer Assay was 93%, and all gene assays were within 36% of that value. High analytical sensitivity, wide linear range (at least 10 logs) and low bias (under 9.7%) demonstrate that the assay is able to measure accurately gene expression on a wide population range using a limited amount of RNA.7
Clinical Validation

Two studies have been completed that assessed the clinical validity of the Oncotype DX® Genomic Prostate Score.9,12

Study 1. Investigators at the University of California San Francisco enrolled a contemporary cohort of 395 early stage prostate cancer patients undergoing radical prostatectomy from 1997 to 2011.13 Patients were eligible if they were candidates for active surveillance based on conventional criteria (NCCN® very-low/low/low-intermediate risk). Patients were excluded from the study if any of the following were present: (1) biopsy Gleason score >3+4, (2) biopsy Gleason score 3+4 with high-volume disease, (3) clinically advanced or node-positive disease, (4) PSA >20, (5) unavailable or insufficient tissue (<1mm biopsy tumor length), or (6) missing RP or biopsy for central review. All patients had undergone radical prostatectomy within six months of initial biopsy. The GPS was a statistically significant predictor of adverse pathology, defined as Gleason 4+3 or higher and/or non-organ confined disease (p=0.002). On pre-specified binary logistic regression analyses controlling for Gleason score, the assay predicted high-grade (primary Gleason 4/5) disease and/or pT3 disease, with OR 2.5 (1.6-3.9) and 2.2 (1.5-3.3), respectively, for each 20-unit increase in the assay score. The investigators concluded that Oncotype DX GPS adds independent predictive information beyond all standard clinical and pathological data.12

Study 2. Cullen et al. studied 382 patients enrolled in the Center for Prostate Disease Research longitudinal study, performed at two US military medical centers (Walter Reed National Military Medical Center and Madigan Army Medical Center) between 1990 and 2011.9 They found that Oncotype DX GPS Assay was (1) strongly associated with and an independent predictor of BCR (HR/20 GPS units=2.9; 95% CI: 2.0, 4.2; p<0.001), (2) reConfirmed as a strong and independent predictor of adverse pathology (AP) at surgery (HR/20 GPS units=3.2; 95% CI: 2.1, 5.0; p<0.001), and (3) significantly associated with metastasis (HR/20 GPS units=3.8; 95% CI: 1.1, 12.6; p<0.001). The investigators concluded that the association of GPS with near- and long-term clinical end points establishes the assay as a strong independent measure of PCA aggressiveness. Tumor aggressiveness, as measured by GPS, and outcomes were similar in African-American men and Caucasian men in this equal-access health care system.9

Two additional studies assessed the consistency of results in specific patient subgroups. Klein et al. quantified gene expression by RT-PCR for three studies—a discovery prostatectomy study, (n = 441), a biopsy study (n = 167), and the prospectively designed, independent clinical validation study (n = 395) described as Study 1 above.12 Besides results already reported above, this study showed that risk prediction was robust in Gleason 4+3, high stage disease (pT3a), and high-grade and/or high-stage disease. Also, for each analysis, the combined CAPRA plus GPS model yielded greater net benefit than the CAPRA score alone, indicating improved discrimination and calibration. Badani et al. reported on the first 750 patient samples tested since the assay was made available in May 2013 that met clinical and pathology submission criteria. They concluded that a wide range of GPS values was observed in each NCCN risk group and in tumors with only 1 mm of tumor length, enabling clinically meaningful refinement of risk.13

Clinical Utility

Three studies evaluated physician perception of the assay’s utility in clinical practice, and the impact that the assay results have on physician treatment recommendations and patient treatment decisions.

Study 1. Andriole et al. conducted an online survey of 18 urologists from 9 community and academic centers, between July and November, 2013.14 They reported that physicians had little or no previous experience with the assay. The physicians felt confident to interpret the report and integrate the results into clinical decision making. When the GPS predicted a lower risk than the patient’s clinical risk category, Active Surveillance recommendations increased from 33% (12/36) to 64% (23/36) of recommendations. In cases where urologists changed their treatment recommendation after receiving GPS assay results, changes in recommendation were directionally consistent with the result.14

Study 2. Badani et al. separately reported on 158 patients enrolled from three sites (community-based: Delaware Valley Urology and Orange County Urology and one academic: New YorkPresbyterian Hospital/Columbia University). GPS, resulted in a treatment recommendation change in 26% of men with newly diagnosed prostate cancer. The NCCN low risk group saw the greatest change (37%) post-GPS. In 17/57 (30%) of patients initially recommended RP, treatment recommendations were changed to AS post-GPS. In 85% of cases, urologists indicated greater confidence in treatment recommendations and found incorporation of the GPS useful in 78% of cases, including where biological risk confirmed clinical risk category.15

Study 3. A chart review study by Dall’Era et al. documented real world experience with GPS from data collected in medical records for men with NCCN very-low, low, or intermediate early-stage prostate cancer. Comparison of men tested with GPS to a control population of untested patients revealed a significant shift toward AS in favor of the tested group (24% absolute increase, 56% relative increase). The percentage of men actually undergoing AS increased over baseline in each NCCN risk group.16

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References


5. Klein E, T TM, S SF. Quantitative gene expression in primary and highest Gleason pattern cancers identifies genes associated with clinical recurrence after radical prostatectomy. American Society of Clinical Oncology; June 2011; Chicago, IL.


8. Cooperberg M, Simko J, Falzarano S. Development and validation of the biopsy-based genomic prostate score (GPS) as a predictor of high grade or extracapsular prostate cancer to improve patient selection for active surveillance. American Urology Association 2013; San Diego, CA.


11. Simko J, Cooperberg M, Cowan J. A Biopsy-Based Molecular Diagnostic Test Predicts Aggressive Prostate Cancer Despite Variability in Pathology Assessment. American Society of Cancer Oncology; 2014; Chicago, IL.


Healthcare Provider Enrollment - Form 1
Oncotype DX® Certification and Training Registry (Oncotype DX CTR)

If you opt out of using an electronic signature within OncotypeDXctr.com please print, sign and fax Form 1 to Genomic Health at 650-362-6487

Physician Name:  

NPI:  

Email:  

Full Address:  

By signing below, I agree to be enrolled in and I acknowledge that I have been trained on and will comply with the terms and Medicare mandated requirements of the Oncotype DX Prostate Cancer Assay Certification and Training Registry (Oncotype DX CTR) Program, including the items set forth below:

1. Program Guide
2. Training Package
3. Healthcare Provider Enrollment (Form 1)
4. Clinical Criteria for Medicare (Form 2)
5. Adverse Event Report (Form 3)
6. Patient Guide

Physician Signature: ____________________________ Date: ____________________________

Physician Name (please print): _______________________________________________________

Genomic Health is required to keep a signed copy on file. If faxing please retain a copy for your records.
Local Coverage Decision (LCD) L36153 requires that healthcare providers who are registered in the Oncotype DX Prostate Cancer Assay Certification and Training Registry (Oncotype DX Prostate Cancer Assay CTR) collect and report data to Palmetto GBA on those Medicare patients tested under the Oncotype DX Prostate Cancer Assay CTR. This Clinical Criteria Form is provided in order to capture data for Medicare patients being followed in the Oncotype DX Prostate Cancer Assay CTR.

Pursuant to the Medicare LCD, Genomic Health has agreed to receive these reports for the purpose of reporting to Palmetto GBA on your behalf in compliance with the LCD. To protect the confidentiality of protected health information (PHI), all data collected will be de-identified and aggregated for reporting to Palmetto GBA. If you have any questions, you may contact customer service at 1-877-662-6897.

**Patient Name: ____________________________  DOB: ___________  HIC/Ins ID#: ____________________________

**Date of current biopsy being submitted for Oncotype DX GPS (MM/DD/YYYY): ___________  ___________  ___________

- [ ] The patient’s first biopsy, OR
- [ ] A repeat biopsy, date of initial biopsy (if known) ___________  ___________  ___________
  - [ ] Trus-guided (not TURP)
  - [ ] Extended pattern (12 cores)

**Indications for 1st biopsy** (specific findings provided)
- [ ] PSA > 3.0 ng/mL
- [ ] Nodule on DRE
- [ ] 1st degree relative diagnosed with prostate cancer

**PLEASE CHECK THE SINGLE APPROPRIATE BOX FOR EACH QUESTION**

**PSA:** ___________ ng/mL  
**PSA Density:**
- [ ] < 0.15 ng/ml/g
- [ ] ≥ 0.15 ng/ml/g

**Biopsy Gleason score:**
- Primary: ___________
- Secondary: ___________
- Gleason sum: ___________

**Biopsy Cores:**
- [ ] # of positive cores ___________
- [ ] # total cores ___________
- [ ] Was any core ≥ 50% positive?  Yes  No

**Clinical Stage:**
- [ ] T1c (Tumor not palpable or visible on imaging, detected by PSA)
- [ ] T2a (Tumor involves half of one lobe or less)
- [ ] T2b (Tumor involves more than half of one lobe but not both lobes)
- [ ] T2c (Tumor involves both lobes)

**Patient’s life expectancy?**
- [ ] ≥ 10 years

As determined by:
- [ ] Social Security Actuarial Table
- [ ] Charlson Comorbidity Index
- [ ] Other ____________________________

**What is your pre-GPS management recommendation?**
- [ ] Active Surveillance
- [ ] Radical Prostatectomy
- [ ] External Beam Radiation
- [ ] Brachytherapy
- [ ] Other ____________________________

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This patient is a candidate for either active surveillance or definitive therapy (e.g., radical prostatectomy, radiation therapy or brachytherapy) for prostate cancer. Patient has not received pelvic radiation or androgen deprivation therapy prior to biopsy. If the patient opts for active surveillance, he will be managed in accordance with the NCCN active surveillance guidelines.

I understand that I, the treating physician, must report cancer progression, prostate cancer metastasis, and prostate cancer specific death in any patient who has a very low or low risk of adverse pathology on GPS and chooses active surveillance for initial management.

To the best of my knowledge, the information above is accurate.

Healthcare Provider Signature:__________________________________ Date (MM/DD/YYYY):_____/_____/______

Healthcare Provider Name (printed):______________________________________ NPI#_______________________

Criteria for Coverage MolDX: Genomic Health OncoType DX Prostate Cancer Assay LCD# L36153

The OncoType DX Prostate Cancer Assay is covered only when the following clinical conditions are met:

- Needle biopsy with localized adenocarcinoma of the prostate (no clinical evidence of metastasis or lymph node involvement), and
- Patient stage as defined by one of the following:
  - Very Low Risk Disease (T1c AND Gleason Score ≤ 6 AND PSA < 10 ng/mL AND < 3 prostate biopsy cores positive 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), Patient has an estimated life expectancy of > 5 years.
- Patient is a candidate for, and is considering conservative therapy and would be eligible for definitive therapy (radical prostatectomy, 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 the Genomic Health OncoType DX Prostate Cancer Assay Certification and Training Registry (OncoType DX CTR), and
- Submit for each patient
- Patient is monitored for disease progression according to active surveillance guidelines as recorded in NCCN guidelines, and
- Physician must report the development of metastasis or prostate specific cancer mortality in patients not treated definitively who were deemed NCCN Very-Low and Low risk by the assay.

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Adverse Event Report (AER) - Form 3
Oncotype DX® Certification and Training Registry (Oncotype DX CTR)

Please complete, sign and fax to Genomic Health at (650) 362-6487

Local Coverage Decision (LCD) L36153 requires that healthcare providers who are registered in the Oncotype DX Prostate Cancer Assay Certification and Training Registry (Oncotype DX Prostate Cancer Assay CTR) collect and report data to Palmetto GBA on those Medicare patients tested under the Oncotype DX Prostate Cancer Assay CTR.

This Adverse Event Report form is provided as a means to report cancer progression, metastasis, and/or prostate cancer specific mortality in Medicare patients in the Oncotype DX Prostate Cancer Assay CTR who elect active surveillance in the setting of a Genomic Prostate Score (GPS) consistent with very low or low risk prostate cancer.

Pursuant to the Medicare LCD requirements, Genomic Health has agreed to receive these reports for the purpose of reporting to Palmetto GBA on your behalf in compliance with the LCD. To protect the confidentiality of protected health information (PHI), all data collected will be de-identified and aggregated for reporting to Palmetto GBA. If you have any questions, you may contact Genomic Health Customer Service.

Patient Oncotype DX Accession ID: _______________________________ Patient DOB___________

1. Was the GPS result in this patient consistent with very low or low risk disease? □ Yes □ No

2. Did the patient initially select active surveillance for management of his prostate cancer? □ Yes □ No

3. Did the patient ever have any treatment for prostate cancer? □ Yes (go to 3a) □ No (go to 4)

3a. What treatment(s) did the patient receive for prostate cancer? (check all that apply)

□ Active Surveillance
□ Radical Prostatectomy
□ External Beam Radiation
□ Brachytherapy
□ Other______________________________

4. On what date was the adverse event diagnosed? (MM/DD/YYYY): ____/____/____

5. What was the adverse event?

□ Prostate Cancer Progression
□ Prostate Cancer Metastasis
□ Prostate Cancer Specific Mortality

To the best of my knowledge, the information above is accurate.

Healthcare Provider Signature: ___________________________________________ Date:____/____/____

Healthcare Provider Name (printed):________________________________________

Healthcare Provider Phone Number:__________________________ Email:_____________________________________

Please complete, sign and fax to Genomic Health at (650) 362-6487

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Patient Guide
Oncotype DX® Certification and Training Registry (Oncotype DX CTR)

Instructions for Healthcare Providers:
Provide a copy of this guide upon counseling Medicare patients

Oncotype DX Prostate Cancer Assay Patient Guide for Medicare Beneficiaries

Introduction: This guide educates Medicare beneficiaries diagnosed with NCCN® Very-Low and Low risk prostate cancer about the Oncotype DX Prostate Cancer Assay. This biopsy-based genomic test can help you and your doctor make a better informed treatment decision based on the unique biology of your tumor.

Purpose: The Oncotype DX Prostate Cancer Assay harnesses the power of genomics to provide a more precise and accurate assessment of risk based on individual tumor biology. Using a minimal tissue sample from a needle biopsy, the test builds on traditional clinical pathologic factors to provide additional, clinically relevant insight into the underlying prostate tumor biology, enabling patients and their physicians to make treatment decisions with greater confidence.

Test Results: The result of the Oncotype DX prostate cancer test is provided as a Genomic Prostate Score (GPS). Your GPS is a measure of the activity of 17 genes within your tumor, and can help to predict the aggressiveness of your prostate cancer. GPS can be used along with other clinical risk factors to personalize your prostate cancer treatment based on the underlying biology of your tumor.

Treatment Plan: The Oncotype DX prostate cancer test is an important tool that may be used when deciding whether to pursue active surveillance or immediate treatment. When deciding how to manage your prostate cancer, you and your doctor should consider your GPS in combination with other laboratory test results, your personal preferences, and your overall health. All management options include risks and benefits. Oncotype DX may help you and your doctor make a more informed choice that is in line with your goals.

Safe Use Conditions: The Oncotype DX GPS does not diminish the importance of your doctor’s judgement and clinical/pathologic information including PSA, Gleason score, and clinical stage. Regardless of which treatment option you pursue, it is important that you maintain regular contact with your doctor to ensure proper follow-up for your prostate cancer.