DECIPHER BIOSCIENCES

PROGRAM GUIDE

DECIPHER CERTIFICATION AND TRAINING REGISTRY (DECIPHER CTR)

This Program Guide provides a step-by-step overview of the operational aspects of the Decipher CTR, including how to (1) enroll as a healthcare provider and receive training on appropriate use of Decipher testing, (2) report any adverse events as a result of using Decipher, and (3) counsel and appropriately monitor your Medicare patients who have received Decipher testing.

Due to the complicated nature of management decisions pertaining to utilization of the Decipher test and the potential to miss salvageable prostate cancer tissue, testing must be furnished only by physicians who are enrolled in the Decipher CTR for Medicare beneficiaries. The Decipher CTR serves as a control to ensure appropriate selection of patients, compliance with management decisions, and stringent follow-up to confirm that the benefits of the test outweigh the risks.

The goals of the Decipher Certification and Training Registry are as follows:

- To ensure that physicians understand the limitations of the test based on its validation in retrospective and heterogeneous patient populations, **and**
- To inform prescribing physicians and patients on the safe-use conditions for Decipher, **and**
- To avoid missing clinically relevant events in Decipher low-risk patients such as development of metastatic prostate cancer or cancer related death with associated increased morbidity and mortality

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As the sponsor of Decipher CTR, Decipher Biosciences is 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.

DECIPHER BIOSCIENCES

PROGRAM GUIDE

DECIPHER CERTIFICATION AND TRAINING REGISTRY (DECIPHER CTR)

1. Healthcare Provider Enrollment:

A. All Decipher CTR documents must be carefully reviewed.
B. Necessary training must be completed by reviewing all materials on DecipherCTR.com.
C. A Healthcare Provider Enrollment form (page 10) must be completed and returned to Decipher Biosciences by fax at 855.324.2768 or email at customersupport@decipherbio.com.

2. Decipher Prostate RP Testing:

A. Decipher Prostate RP is covered by Medicare for high-risk patients after radical prostatectomy (RP) with post-operative adverse pathology.
B. To order Decipher Prostate RP for Medicare beneficiaries, the healthcare provider must be enrolled in the Decipher CTR and complete a Decipher Prostate Test Requisition Form (page 8) with pre-treatment decision.
C. Patients should be appropriately counseled on:
   a. Benefits and risks of Decipher Prostate RP testing
   b. Decipher Prostate RP test results
   c. Need for additional follow-up and appropriate treatment options
D. As required by the CTR, all adverse outcomes experienced by Medicare beneficiaries that were tested with Decipher Prostate RP must be reported.

3. Observational Data Collection/Reporting:

A. Upon determining a treatment plan after running Decipher Prostate RP, the Post-Test Treatment form (page 11) must be completed and returned to Decipher Biosciences by fax at 855.324.2768 or email at customersupport@decipherbio.com. This form can also be downloaded from decipherbio.com.
B. Any distant metastases or prostate cancer related deaths in patients who were deemed low-risk by the assay must be reported immediately.
C. To aid in the follow-up process of checking for adverse events, a cumulative list of patients tested with Decipher Prostate RP that received a low Decipher score will be sent to each healthcare provider that is enrolled in the program every six months.
D. An Adverse Event Report (AER) form (page 12) must be completed and returned to Decipher Biosciences by fax at 855.324.2768 or email at customersupport@decipherbio.com. This form can also be downloaded on decipherbio.com.

4. Program Compliance:

A. The LCD(s) providing coverage for Decipher Prostate RP require healthcare providers to comply with all obligations of the Decipher CTR to maintain their certification.
B. As the sponsor of the Decipher CTR, Decipher Biosciences is responsible for ensuring continued compliance from participating healthcare providers, and may contact you occasionally to request information or provide educational materials for the provider or patient.
C. If registered healthcare providers repeatedly fail to comply with the terms of the LCD and the Decipher CTR, Decipher Biosciences is required to take appropriate measures to reach compliance, including implementation of corrective action plans and, if necessary, de-certification.

TRAINING PACKAGE

DECIPHER CERTIFICATION AND TRAINING REGISTRY (DECIPHER CTR)

The Decipher Certification and Training Registry (CTR) was established to enable Medicare coverage for eligible patients. Under Local Coverage Determination (LCD) L36343, Decipher Prostate RP is considered "reasonable and necessary" for Medicare patients who meet the coverage criteria when ordered by a physician certified in the Decipher CTR.

DECIPHER BIOSCIENCES

Section 1. Overview of Decipher Prostate RP

Test Description

Decipher Prostate RP is a whole-transcriptome assay that uses oligonucleotide microarray technology to capture 1.4 million genomic biomarkers and measure a 22-gene expression signature from RNA extracted from formalin-fixed, paraffin-embedded (FFPE) prostate cancer tissue samples. The biomarkers that comprise the test span 7 biological pathways including invasion and metastasis, androgen signaling, metabolism, angiogenesis, proliferation and cell death, growth and differentiation, and immune activity and response. Decipher provides an independent, individualized, and continuous risk estimate of metastasis and prostate cancer specific mortality (PCSM) with higher accuracy than current risk stratification tools and nomograms that incorporate only clinical features.

Test Performance

Decipher Prostate RP test performance was assessed by analytical validity, clinical validity, and clinical utility studies in more than 1,900 unique, high-risk, post-RP patients from multiple, diverse cohorts. The assay was developed using metastasis as the clinical endpoint, and the result provides risk estimates of metastasis and prostate cancer specific mortality (PCSM) after RP. Importantly, Decipher Prostate RP has a higher accuracy than clinical and pathological factors that are currently used in standard practice (including pre-operative PSA, surgical pathology, and Gleason Score) in the prediction of clinical outcomes, leading to re-classification and further stratification of clinically-determined patient risk, and a strong association with patient outcomes. Most importantly, Decipher Prostate RP has demonstrated the ability to alter treatment-based decisions for prostate cancer patients, ultimately resulting in improved patient outcomes.

Section 2. Limitations of the Decipher Test

Clinical studies have demonstrated the ability of Decipher Prostate RP to accurately estimate patient risk and influence treatment decisions. The number of prospective studies, however, is limited, as most require 10 years or more to complete. Thus, the majority of Decipher Prostate RP clinical studies are blinded, retrospective studies that were conducted on patient cohorts that contain inevitable heterogeneities. However, due to the robustness of the retrospective studies and strength of the data, both Noridian and Palmetto GBA, contractors for Centers for Medicare & Medicaid Services (CMS), believe that clinical utility can be extrapolated from the results.

Section 3. Important Safety Information

When applying retrospective analysis to prospective treatment, there is concern that the treatment pathway of the patient may be altered due to a single test result. Consequently, the appropriate use of Decipher and resulting treatment outcomes must be clearly understood by ordering physicians, making education and training very important.

Section 4. Patient Eligibility – Indications for Use Under Decipher LCD ID L36343

Decipher Prostate RP is covered by Medicare only when the following clinical conditions are met:

- Patient with prostate cancer who has undergone a RP within the previous 60 months and is being considered for postoperative secondary therapy due to one or more cancer-recurrence risk factors, AND
- Patient must have achieved initial PSA nadir (defined PSA at or below 0.2 ng/ml) within 120 days of RP surgery, AND
- Patient must not have any evidence of distant metastasis, AND
- Patient must not have received any neo-adjuvant treatment prior to surgery, AND
- Decipher Prostate RP is performed on a patient's RP specimen, AND
- Patient's surgical pathology report or medical records must have documented presence of adverse pathology:
  - Pathological stage T2 disease with a positive surgical margin, OR
  - Pathological stage T3 disease or higher (extra-prostatic extension, seminal vesicle invasion,

bladder neck invasion), OR
  - Rising PSA after initial PSA nadir, AND
- Testing has been ordered by a physician who is certified in the Decipher CTR.

Section 5. Patient Management

As part of the CTR requirements and to ensure that the benefits of Decipher Prostate RP testing outweigh risks, physicians should discuss risks and appropriate monitoring with their patient.

Interpretation of Decipher Results
Post-operative setting (Adjuvant):
The Decipher RP test classifies patients that are Decipher low-risk as those who can delay or defer radiation after prostatectomy, and those that are Decipher high-risk as those who would potentially benefit from adjuvant or immediate RT with or without additional therapies. For Decipher high-risk patients, a significant difference in metastasis was observed at 5 years for the patients who received adjuvant RT (6%) compared to those who received salvage RT (23%) (p=0.008). Furthermore, the hazard ratio (HR) for adjuvant RT relative to salvage RT is 0.2 for Decipher high-risk men, indicating that the men who received adjuvant RT had 80% reduction in risk of metastasis compared to those who received salvage RT.[1]

Post-Biochemical Recurrence (BCR) setting (Salvage):
Post-BCR, Decipher low-risk patients may be treated with salvage RT alone, while Decipher high-risk patients may require intensification of treatment by adding systemic therapy.[2,3] In patients who received no prior RT until treatment with salvage RT after BCR, it was reported that Decipher low-risk patients had a 3% cumulative incidence of metastasis at 5 years, while Decipher high-risk patients had 33% incidence. Furthermore, timing of salvage radiation for Decipher low-risk patients did not impact the incidence of metastasis, whereas Decipher high-risk patients significantly benefited from earlier RT (incidence of 5-year metastasis was 8% in Decipher low-risk patients vs. 29% in Decipher high-risk, p=0.031).[3,4]

Safe Use
Decipher Prostate RP test results do not detract from treatment recommendations from the physician or other clinical and pathological indicators. Regardless of treatment decision, prostate cancer must be monitored closely, and regular follow-up appointments should be maintained.

Section 6. Decipher Prostate RP Peer-Reviewed Scientific Evidence

Decipher Prostate RP Clinical Validity
The 22 genes that comprise the Decipher test were identified from differential expression analysis in metastatic and non-metastatic primary tumors, respectively, from 621 post-RP prostate cancer patients (Mayo Clinic Comprehensive Cancer Center, 1987-2001).[5,6] These genes span across 7 biological pathways, including invasion and metastasis, androgen signaling, metabolism, angiogenesis, proliferation and cell death, growth and differentiation, and immune activity and response, incorporating both coding and non-coding RNA. Importantly, the assay was developed as a metastasis-specific signature, which is critical for the determination of true metastatic risk. A clinical endpoint such as BCR cannot predict the ultimate clinical course of the patient and is, therefore, a non-specific endpoint.[7–9]

Subsequent to its discovery, Decipher was clinically validated in the post-RP setting in numerous high-risk, diverse patient cohorts, and was shown to independently and consistently predict metastasis or PCSM in patients with postoperative APF or persistent/recurrent PSA.[1–4,6,7,10–17] Prognostic performance of Decipher, as measured by area-under-the-curve (AUC) analyses, was more accurate (0.75-0.86) in predicting post-RP risk of 5-year metastasis and PCSM than the clinical and pathological risk factors currently used in standard practice, including pre-op PSA level (0.51-0.62), APF at the time of RP (0.58-0.65), and Gleason score (0.64-0.71).[1–3,5–7,12,14,15] All clinical validation studies showed strong

positive correlation between Decipher Prostate RP risk classification and clinical outcomes.[1–3,6,7,12,14–16] Decipher low-risk patients had as low as 0% 5-year cumulative incidence of metastasis compared with up to 54% in Decipher intermediate/high-risk patients.[1–3,6,7,14–16,18] Similarly, there was as low as 6% 10-year cumulative incidence of PCSM in Decipher low-risk patients and as high as 45% in Decipher high-risk patients.[4,11]

Importantly, studies show that Decipher high-risk men benefit from earlier RT, demonstrating that timing of RT can influence clinical outcomes.[1,3] A retrospective study comparing adjuvant versus salvage RT showed that Decipher high-risk patients significantly benefited from adjuvant RT. Decipher high-risk men who received adjuvant RT had a 5-year metastasis rate of 6%, while those who received salvage RT had a 23% rate. In addition, the men who received adjuvant RT had an 80% reduction in metastatic risk, as determined by hazard analysis.[1] In a retrospective, salvage clinical setting, Decipher high-risk men had significantly better outcomes when treated with early salvage RT, as opposed to delayed salvage.[3] On the other hand, early RT in adjuvant or salvage settings did not affect the rate of metastasis for Decipher low-risk patients, suggesting that these men can be safely observed and treated with delayed salvage RT.[1]

In summary, clinical validation studies demonstrate that post-RP, Decipher low-risk patients can safely delay or defer treatment to preserve quality of life, and Decipher high-risk patients may benefit from early radiation or treatment intensification.

Decipher Clinical Utility
In addition to the clinical validation studies, clinical utility studies were designed to determine the ability of Decipher to alter clinical decision-making and improve patient outcomes. Clinical utility regarding Decipher can be extrapolated from the completed prospective and retrospective studies, and evidence will continue to increase as ongoing studies are completed.

The prospective, multi-center clinical utility studies, PRO-ACT and PRO-IMPACT, were designed to investigate the influence of Decipher on post-RP treatment decisions for high-risk patients in various RT settings (adjuvant, salvage, with or without ADT), and have demonstrated that Decipher risk estimates strongly influenced RT recommendations: Decipher high-risk men are likely to be referred for RT, and Decipher low-risk men are likely to be referred for observation.[19,20] Furthermore, multivariate analysis confirmed that Decipher significantly decreased RT-related decisional conflict and was the only significant predictor of treatment recommendations.[19,20]

Retrospective studies including more than 110 physicians from tertiary and community cancer centers across the United States have also determined that Decipher Prostate RP significantly influenced patient treatment recommendations in post-RP adjuvant and salvage settings. Overall, ~43% (ranging from 31%-53%) changed their treatment recommendations after considering Decipher test results, generally recommending RT with or without ADT for Decipher high-risk men, and observation for Decipher low-risk men.[8,21,22]

In 2015, a Markov decision analysis study simulated the replacement of population-level risk estimates with individual Decipher risk estimates in 10,000 patients, incorporating findings from the PRO-ACT prospective trial. It was determined that the use of Decipher significantly improved model outcomes, with a 12% relative increase in the 5-year recurrence-free survival probability, and a 4% relative reduction in the 5-year probability of metastatic or lethal disease.[23] A separate study showed that Decipher RP is cost-effective, with an incremental cost-effectiveness ratio (ICER) of $80K, which is well below the ICER benchmark of $100-150K for reasonable long-term monetary value.[24]

The clinical utility of Decipher Prostate RP is currently being evaluated in multiple prospective clinical trials, including G-MINOR (NCT02783950), NRG-GU002 (NCT03070886), RTOG 9601

(NCT00002874), and SAKK09/10 (NCT01272050) to determine the impact of Decipher test results on treatment decisions for high-risk, post-RP patients in various settings, including adjuvant and/or salvage RT with undetectable and/or persistent postoperative PSA, respectively. The outcomes of these studies are predicted to decreaseheterogeneities in study cohorts and provide further confirmation of improved clinical outcomes.

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DECIPHER PROSTATE

DECIPHER PROSTATE REQUISITION FORM
Fax: 855.324.2768 (Toll-Free) or 858.408.7420 (Direct)
Email: orders@decipherbio.com

ALL FIELDS IN THIS BOX ARE REQUIRED

PATIENT INFORMATION

Patient Name		
DOB (MM/DD/YYYY)	Patient Medical Record #	Race/Ethnicity

ORDERING PHYSICIAN INFORMATION

Account #	Office / Practice / Institution Name
Street Address / City / State / ZIP	
Telephone	Fax
Ordering Physician	NPI

BILLING INFORMATION

ICD-10 Primary Diagnosis Code(s)	Bill Type	Secondary Insurance?	Patient Status (for Medicare patients)
☐ C61 MALIG NEO PROSTATE ☐ R97.20 ELEVATED PSA ☐ D07.5 CA IN SITU PROSTATE ☐ Other_____	☐ Insurance ☐ Self-Pay ☐ Medicare - Part B ☐ Client Bill	☐ Yes ☐ No	☐ Outpatient ☐ Hospital Inpatient - Date of Discharge _____

DECIPHER TESTING. Select Decipher Prostate Biopsy OR Decipher Prostate RP.

☐ Decipher Prostate Biopsy
See reverse side for test description.

Most Recent PSA (ng/mL)	Date of Biopsy (MM/DD/YYYY)	Radiation or Hormone Therapy Prior to Biopsy?
		☐ Yes ☐ No

Evidence of Distant Metastasis or Lymph Node Involvement?	Clinical Stage (Select one)
☐ Yes ☐ No	☐ T1c ☐ T2a ☐ T2b ☐ T2c ☐ Other_____

OR

☐ Decipher Prostate RP
See reverse side for test description.

Most Recent Post-Op PSA Value (ng/mL) Date (MM/DD/YYYY)	Date of RP Surgery (MM/DD/YYYY)	Radiation or Hormone Therapy Prior to Surgery?
		☐ Yes ☐ No

Evidence of Distant Metastasis?	Clinical Information (select all that apply)
☐ Yes ☐ No	☐ Positive Surgical Margins ☐ Extraprostatic Extension ☐ Seminal Vesicle Invasion ☐ Bladder Neck Invasion ☐ Rising PSA / Biochemical Recurrence

PHYSICIAN SIGNATURE AND LETTER OF MEDICAL NECESSITY

MEDICAL JUSTIFICATION. Patient is being considered for the treatment below, and genomic testing is indicated to help determine the optimal treatment plan: (select one)

Decipher Prostate Biopsy			Decipher Prostate RP	
☐ Conservative Management (Active Surveillance, Observation)	☐ Definitive Therapy (EBRT, Brachytherapy, Radical Prostatectomy)	☐ Definitive + Systemic Therapy (EBRT + Short or Long Term ADT, EBRT + Brachytherapy + Short or Long Term ADT)	☐ Initial Treatment Post-RP (Observation, EBRT +/- ADT)	☐ Salvage Therapy (EBRT +/- ADT)

I confirm that this test is medically necessary and results will be used for treatment decisions and medical management for the patient. Decipher enables me to determine which patients may be safely surveilled or observed and which patients should be considered for aggressive management such as radiation therapy or hormone therapy. For patients who are candidates for active surveillance or definitive therapy I confirm that the patient has an estimated life expectancy ≥ 10 years. Decipher helps me and my patient determine the best clinical course for management of his prostate cancer. I hereby authorize testing and an informed consent has been obtained. I confirm that I have on file the patient's assignment of benefits authorizing benefits to be paid to ancillary service providers such as Decipher Biosciences. I authorize Decipher Biosciences to release information provided by me to process the claim for this service. I understand that, as part of the Decipher testing, additional genomic information will be collected as part of Decipher GRID and may be provided as Research Use Only (RUO) data.

For Medicare Beneficiaries being tested with Decipher Prostate RP, I further certify that I have completed requisite training and have enrolled in the Decipher CTR program for the Decipher Prostate RP. (The patient Medicare eligibility criteria is provided on the back side of this form.)

Ordering Physician Signature	Date (MM/DD/YYYY)

GRID PROFILE (See description on reverse)

☐ Check here if the patient has authorized you to receive their GRID Profile, which is RUO and not to be used for treatment decisions or medical management.

THE FOLLOWING MUST BE ATTACHED

- ☐ Demographic/face sheet
- ☐ Most recent office note
- ☐ Pathology report
- ☐ Copy of insurance card(s), if applicable
- ☐ The last three PSA results if Decipher is being ordered for rising PSA/biochemical recurrence

PATHOLOGY / SPECIMEN INFORMATION. Complete only if pathology report is not attached.

Laboratory	Specimen ID
Telephone	Fax

DECIPHER PROSTATE BIOPSY AND DECIPHER PROSTATE RP DESCRIPTIONS

Decipher® uses an oligonucleotide microarray to measure the expression of up to 1.4 million RNAs (e.g., mRNA, lncRNA) extracted from formalin-fixed, paraffin-embedded (FFPE) prostate specimens. Decipher testing on tumor specimens provides the probability of high-grade disease at radical prostatectomy (biopsy specimens only), 5-year probability of clinical metastasis, and 10-year prostate cancer specific mortality. A gene expression signature is used to generate the Decipher score, which ranges from 0 to 1.0. Decipher is intended for use by the physician and patient as an adjunct to conventional clinical and pathological variables currently used for determining prognosis and treatment of prostate cancer patients at time of biopsy or after radical prostatectomy (RP).

- Decipher Prostate Biopsy predicts a patient's risk for metastasis or prostate cancer mortality, as well as high-grade disease at RP, using the gene expression profile of FFPE prostate cancer tissue samples collected at biopsy. Decipher Prostate Biopsy classifies as low risk those who may be safely followed with active surveillance, or as high risk those who would potentially benefit from immediate treatment.
- Decipher Prostate RP predicts a patient's risk for metastasis or prostate cancer mortality for men with adverse pathology or PSA persistence / recurrence following RP using the gene expression profile of FFPE prostate cancer tissue samples collected at RP. Decipher Prostate RP classifies as low risk those who may be safely observed, or as high risk those who would potentially benefit from treatment or treatment intensification.

GRID PROFILE DESCRIPTION

The Decipher assay collects up to 1.4 million data points for each patient when the Decipher test is performed, and such data is used to create the GRID Tumor RNA Expression Profile (GRID Profile). The GRID Profile is a summation of genomic signatures and biomarkers for Research Use Only. Physicians can access their patient's GRID Profile with their patient's authorization (in a form and format that complies with HIPAA and state law) by contacting Decipher Biosciences. The genomic data will be securely stored in the Decipher GRID database and will be de-identified for any research use. For more information, please visit: **www.decipherbio.com**

ORDER ACCEPTANCE CRITERIA

Orders submitted to Decipher Biosciences for Decipher testing must meet the criteria below.

- Decipher Prostate Biopsy. FFPE blocks, punch cores or unstained slides are accepted from biopsy specimens where the patient has been diagnosed with prostate cancer with a) Gleason score of less than or equal to 6 (grade group 1) or b) Gleason score of 3 + 4 = 7 (grade group 2) or c) Gleason score of 4 + 3 = 7 where the most recent serum PSA level is no greater than 20 ng/mL and the stage is T2c or less.
- Decipher Prostate RP. FFPE blocks, punch cores, whole mounts or unstained slides are accepted from RP specimens where the patient meets the Medicare indications below.

MEDICARE INDICATIONS FOR DECIPHER PROSTATE BIOPSY

VERY LOW AND LOW RISK DISEASE
Medicare Beneficiaries Eligibility - LCD L37785

The Decipher Biopsy assay is covered for men with NCCN low risk and very low risk prostate cancer 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
- FFPE prostate biopsy specimen with at least 0.5 mm of cancer length, and
- Patients with low risk or very low risk as defined by the NCCN as follows:
  - Low Risk:
    - Stage T1 or T2a
    - PSA less than 10 ng/mL
    - Gleason score 6 or less (grade group 1) OR
  - Very Low Risk:
    - Stage T1c
    - PSA less than 10 ng/mL
    - Gleason score 6 or less (grade group 1)
    - Not more than two cores with cancer
    - Less than or equal to 50 percent of core involved with cancer
    - PSA density less than 0.15
- 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 prostatectomy, radiation therapy or brachytherapy), and
- Result will be used to determine treatment between definitive therapy and conservative management by active surveillance (AS) and
- Patient has not received pelvic radiation or androgen deprivation therapy prior to the biopsy, and

Patient is monitored for disease progression based on the established standard of care, including at least a repeat biopsy at 1 year.

FAVORABLE AND UNFAVORABLE INTERMEDIATE RISK DISEASE
Medicare Beneficiaries Eligibility - LCD L38029

The Decipher Biopsy test is covered for men with prostate cancer 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
- FFPE prostate biopsy specimen with at least 0.5 mm of cancer length, and favorable or unfavorable intermediate risk disease as defined in the most recent available NCCN guideline 2018 V4, and
- Patient has an estimated life expectancy of greater than or equal to 10 years, and
- Patient is a candidate for definitive therapy (RP +/- PLND, EBRT + ADT, or EBRT + brachytherapy +/- ADT), and
- Result will be used to determine treatment among definitive therapy modalities or observation, and
- Patient has not received pelvic radiation or androgen deprivation therapy prior to the biopsy, and
- Patient is monitored for disease progression according to established standard of care

MEDICARE INDICATIONS FOR DECIPHER PROSTATE RP

Medicare Beneficiaries Eligibility - LCD L35868

The Decipher Prostate RP assay is covered by Medicare only when the following clinical conditions are met:

- Patient with prostate cancer who has undergone a RP within the previous 60 months and is being considered for postoperative secondary therapy due to one or more cancer recurrence risk factors, and
- Patient must have achieved initial PSA nadir (defined as PSA at or below 0.2 ng/ml) within 120 days of RP surgery, and
- Patient must not have any evidence of distant metastasis, and
- Patient must not have received any neoadjuvant treatment prior to surgery, and
- Decipher GC [Genomic Classifier] is performed on a patient's RP specimen, and
- Patient's surgical pathology report or medical records must have documented presence of adverse pathology:
  - Pathological stage T2 disease with a positive surgical margin, or
  - Pathological stage T3 disease (e.g., extraprostatic extension, seminal vesicle invasion, bladder neck invasion), or
  - Rising PSA after initial PSA nadir, and
- Testing has been ordered by a physician who is certified in the Decipher Certification and Training Registry (CTR)

Testing is performed by Decipher Corp., a Decipher Biosciences company, located at 6925 Lusk Boulevard, Suite 200, San Diego, CA 92121*. The Decipher Corp. laboratory is licensed for high complexity testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

* Prior to January 31, 2020, testing may be performed at 10355 Science Center Drive, Suite 240, San Diego, CA 92121

Decipher Biosciences | 6925 Lusk Boulevard, Suite 200, San Diego, CA 92121
Phone 888.792.1601 | Fax 855.324.2768 (Toll-Free) or 858.408.7420 (Direct)
www.decipherbio.com | orders@decipherbio.com

DECIPHER BIOSCIENCES

HEALTHCARE PROVIDER ENROLLMENT - FORM 1

DECIPHER CERTIFICATION AND TRAINING REGISTRY (DECIPHER CTR)

Physician's Name: _____ NPI: _____ Email: _____

Physician's Address: _____ City: _____ State: ____ Zip: _____

THE GOALS OF THE DECIPHER CERTIFICATION AND TRAINING PROGRAM ARE AS FOLLOWS:

- To ensure that physicians understand the limitations of the test based on its validation through retrospective and heterogeneous patient populations, and
- To inform prescribers and patients on the safe-use conditions for Decipher, and
- To avoid missing clinically relevant development of metastatic prostate cancer or cancer related death with associated increased morbidity and mortality in Decipher low risk patients

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 Decipher Prostate Cancer Classifier Certification and Training Registry (Decipher CTR) Program, including the items set forth below:

1. **Program Guide**
2. **Training Package**
3. **Healthcare Provider Enrollment (Form 1)**
4. **Post-Test Treatment (Form 2)**
5. **Adverse Event Report (Form 3)**

I understand that physicians enrolled in Decipher CTR must report the post-test treatment plan and the adverse events of metastasis and prostate cancer deaths for patients who have been deemed low risk by the Decipher assay to Decipher Biosciences using the Post-Test Treatment and Adverse Event Report Forms immediately. If enrolled physicians have been CTR trained and have tested patients between Nov 27, 2015 and the present date, post-test treatment must be reported, and adverse events must also be reported on patients deemed low risk by Decipher.

_____	_____	____/____/_____
PHYSICIAN NAME (PRINT NAME)	PHYSICIAN SIGNATURE	DATE (MM/DD/YYYY)

Decipher Corp. is required to keep a signed copy on file. If faxing please retain a copy for your records.

PLEASE PRINT, SIGN AND FAX TO: DECIPHER BIOSCIENCES AT 855.324.2768 OR EMAIL TO: CS@DECIPHERBIO.COM

FOR QUESTIONS, CALL CUSTOMER SUPPORT AT 888.792.1601, OPTION 8

DECIPHER BIOSCIENCES
6925 LUSK BOULEVARD, SUITE 200, SAN DIEGO, CA 92121
T 888.792.1601 | F 855.324.2768 | DECIPHERBIO.COM

DECIPHER BIOSCIENCES

POST-TEST TREATMENT - FORM 2

DECIPHER CERTIFICATION AND TRAINING REGISTRY (DECIPHER CTR)

Date: ____/____/_____
MM / DD / YYYY

Patient's Name: _____ Date of Birth: ____/____/_____ Physician's Name: _____
MM / DD / YYYY

Physician's Address: _____ City: _____ State: _____ Zip: _____

Local Coverage Decision (LCD) L36343 requires that healthcare providers who are registered in the Decipher Prostate Cancer Classifier Certification and Training Registry (Decipher Prostate Cancer Classifier CTR) collect and report data to CMS MolDx contractor on those Medicare patients tested under the Decipher Prostate Cancer Classifier CTR.

This Post-Test Treatment form is provided in order to capture treatment administered to the Medicare patients after Decipher test results have been provided to the physician.

Decipher Biosciences has agreed to receive these reports for the purpose of reporting to CMS MolDx contractor 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 CMS MolDx contractor. If you have any questions, you may contact Decipher Customer Service at 888.792.1601.

Accession #: _____ Date of Last Follow Up: ____/____/_____
MM / DD / YYYY

1. Physician treatment recommendations physician and patient agreed upon (post-Decipher testing):

- Observation with PSA Monitoring
- Adjuvant RT
- Salvage RT
- Adjuvant RT + ADT
- Salvage RT + ADT
- ADT Alone
- Adjuvant ADT
- Other: _____

2. Did the patient comply with Management Plan?

Please explain:

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

_____ _____ ____/____/_____
HEALTHCARE PROVIDER NAME (PRINT NAME) HEALTHCARE PROVIDER SIGNATURE DATE (MM/DD/YYYY)

NPI #: _____ Healthcare Provider Phone: (____) ____ - _____ Email: _____

PLEASE FILL OUT THE FORM ABOVE AND RETURN THE SIGNED COPY VIA DOCUSIGN, FAX 855.324.2768 OR EMAIL CS@DECIPHERBIO.COM

FOR QUESTIONS, CALL CUSTOMER SUPPORT AT 888.792.1601, OPTION 8

Testing is performed by Decipher Corp., a Decipher Biosciences company
CS-FRM-0020 v2.0

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DECIPHER BIOSCIENCES

ADVERSE EVENT REPORT (AER) - FORM 3

DECIPHER CERTIFICATION AND TRAINING REGISTRY (DECIPHER CTR)

Date: ____/____/_____
MM / DD / YYYY

Patient's Name: _____ Date of Birth: ____/____/_____ Physician's Name: _____
MM / DD / YYYY

Physician's Address: _____ City: _____ State: _____ Zip: _____

Local Coverage Decision (LCD) L36343 requires that healthcare providers who are registered in the Decipher Prostate Cancer Classifier Certification and Training Registry (Decipher Prostate Cancer Classifier CTR) collect and report data to CMS MolDx contractor on those Medicare patients tested under the Decipher Prostate Cancer Classifier CTR.

This Adverse Event Report form is provided in order to capture undesirable experiences of a serious nature that occur to a Medicare patient being followed in the Decipher CTR.

Decipher Biosciences has agreed to receive these reports for the purpose of reporting to CMS MolDx contractor 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 CMS MolDx contractor. If you have any questions, you may contact Decipher Customer Service at 1.888.792.1601.

Accession #: _____ Date of Last Follow Up: ____/____/_____
MM / DD / YYYY

1. **Decipher Result:**

2. **Evidence of Disease progression, if any:**

Biochemical Failure
Local Recurrence
Development of Metastasis
Prostate Cancer-Specific Death
Non-Prostate Cancer Related Death
N/A, No Evidence of Disease Progression
Other _____

a. On what date was the adverse event diagnosed? ____/____/_____
MM / DD / YYYY

b. What interventions were performed in response, if any (include date of intervention)?

Radiation Therapy, Date: ____/____/_____
MM / DD / YYYY
Androgen Deprivation Therapy, Date: ____/____/_____
MM / DD / YYYY
Secondary Hormonal Manipulation, Date: ____/____/_____
MM / DD / YYYY
Additional Hormonal Manipulation, Date: ____/____/_____
MM / DD / YYYY
Other Systemic Therapy (Sipuleucel, Taxotere), Date: ____/____/_____
MM / DD / YYYY
Other Chemotherapy, Date: ____/____/_____
MM / DD / YYYY
Other: _____

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

_____ _____ ____/____/_____
HEALTHCARE PROVIDER NAME (PRINT NAME) HEALTHCARE PROVIDER SIGNATURE DATE (MM/DD/YYYY)

NPI #: _____ Healthcare Provider Phone: (____) ____ - _____ Email: _____

PLEASE FILL OUT THE FORM ABOVE AND RETURN THE SIGNED COPY VIA DOCUSIGN, FAX 855.324.2768 OR EMAIL CS@DECIPHERBIO.COM

FOR QUESTIONS, CALL CUSTOMER SUPPORT AT 888.792.1601, OPTION 8

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