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

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