Decipher® Prostate

Genomic Classifier

DECIPHER PROSTATE REQUISITION FORM
Fax: 1.858.766.6575 (Direct)
Email: orders@decipherbio.com

ALL FIELDS IN THIS BOX ARE REQUIRED

PATIENT INFORMATION

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

ORDERING PHYSICIAN INFORMATION

Account #	Office / Practice / Institution Name
Address	
Telephone	Fax

Ordering Physician

☐ ☐
☐ ☐
☐ ☐
☐ ☐
☐ ☐ Other _____

BILLING INFORMATION

ICD-10 Primary Diagnosis Code(s)
☐ C61 MALIG NEO PROSTATE ☐ R97.20 ELEVATED PSA
☐ D07.5 CA IN SITU PROSTATE ☐ Other _____

Bill Type
☐ Insurance ☐ Self-Pay
☐ Medicare - Part B ☐ Client Bill

Secondary Insurance?
☐ Yes ☐ No

Patient Status (for Medicare patients)
☐ 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.

Date of Biopsy (mm/dd/yyyy)	Clinical Stage (Select one)	Number of Positive Cores
Most Recent PSA (ng/mL)	☐ T1c ☐ T2a ☐ T2b ☐ T2c ☐ Other	Number of Total Cores

Evidence of Distant Metastasis? ☐ Yes ☐ No

Radiation or Hormone Therapy Prior to Biopsy? ☐ Yes ☐ No

MEDICAL JUSTIFICATION. Patient is being considered for the treatment below and is eligible for treatment intensification as defined on the back side of this form. Genomic testing is indicated to help determine the optimal treatment plan: (select one)

☐ Conservative Management ☐ Definitive Therapy (EBRT & RP) ☐ Definitive (EBRT) + Systemic Therapy (STADT & LTADT)

OR

☐ Decipher Prostate RP

See reverse side for test description.

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

Evidence of Distant Metastasis? ☐ Yes ☐ No

Clinical Information (select all that apply)
☐ Positive Surgical Margins ☐ Extraprostatic Extension
☐ Seminal Vesicle Invasion ☐ Lymph Node Involvement
☐ Rising PSA / Biochemical Recurrence

MEDICAL JUSTIFICATION. Patient is being considered for the treatment below and is eligible for treatment intensification as defined on the back side of this form. Genomic testing is indicated to help determine the optimal treatment plan: (select one)

☐ Observation ☐ Salvage Radiotherapy

STUDY OR TRIAL CODE/NAME (IF APPLICABLE): _____

PHYSICIAN SIGNATURE AND LETTER OF MEDICAL NECESSITY

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, which patients should be considered for definitive therapy such as radical prostatectomy (RP), radiation, or brachytherapy, and which patients should be considered for therapy intensification such as the addition of androgen deprivation therapy (ADT), next generation androgen signaling inhibitors (ARSi), chemotherapy, brachytherapy boost, or an increase in the duration of hormone 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 Veracyte, Inc. and its affiliates. I authorize Veracyte, Inc. and its affiliates 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 (Genomics Resource for Intelligent Discovery) and may be provided as Research Use Only (RUO) data upon request. For Medicare Beneficiaries, I certify that the patient meets the Medicare eligibility criteria provided on the back side of this form.

Ordering Physician Signature	DATE (MM/DD/YYYY)

GRID REPORT (See description on reverse)

☐ **Check here to receive your patient's GRID Report, which is provided as Research Use Only (RUO) data.**

THE FOLLOWING MUST BE ATTACHED

- ☐ Demographic/face sheet
- ☐ Most recent office note
- ☐ Pathology report
- ☐ Copy of insurance card(s), if applicable
- ☐ The first PSA result after RP surgery AND the most recent PSA result if Decipher is being ordered for rising PSA / BCR

PATHOLOGY / SPECIMEN INFORMATION.

Complete only if pathology report is not attached.

Laboratory	Specimen ID
Telephone	Fax

OFFICE CONTACT FOR QUESTIONS ABOUT THIS ORDER:

Name	Phone
Email	

veracyte®

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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 adverse pathology at radical prostatectomy (biopsy specimens only), 5- and 10-year probability of clinical metastasis, and 15-year prostate cancer specific mortality. A 22-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 and Decipher Prostate RP are billed using CPT 81542.

- Decipher Prostate Biopsy predicts a patient's risk for metastasis or prostate cancer mortality, as well as adverse pathology 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 managed with active surveillance or standard of care treatment, or as high risk those who would potentially benefit from immediate treatment or treatment intensification.
- Decipher Prostate RP predicts a patient's risk for metastasis or prostate cancer mortality for men following RP with undetectable, persistently elevated, or rising PSA 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 REPORT DESCRIPTION

The Decipher assay collects 1.4 million data points covering 46,000 coding and non-coding genes for each patient when the Decipher test is performed, and such data is used to create the patient's Decipher GRID Profile. The GRID Report is a summation of transcriptomic gene signatures and biomarkers on the Decipher GRID profile. Physicians can access their patient's Decipher GRID Report for Research Use Only by checking the GRID Report box or by contacting customer support.

ORDER ACCEPTANCE CRITERIA

Orders submitted 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 meets the Medicare indications below.
- 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

Medicare Beneficiaries Eligibility - LCD L38339

Decipher® is covered for men with prostate cancer:

With localized or biochemically recurrent adenocarcinoma of the prostate (i.e., no clinical evidence of metastasis) who have a life expectancy of greater than or equal to 10 years if they are a candidate for and are considering (or being considered for) at least 1 of the following:

- Conservative management and yet would be eligible for definitive therapy (radical prostatectomy (RP), radiation or brachytherapy), or;
- Radiation therapy and yet would be eligible for the addition of a brachytherapy boost, or;
- Radiation therapy and yet would be eligible for the addition of short-term androgen deprivation therapy (ADT), or;
- Radiation therapy with short-term ADT yet would be eligible for the use of long-term ADT, or;
- Radiation with standard ADT yet would be eligible for systemic therapy intensification using next generation androgen signaling inhibitors or chemotherapy, or;
- Observation post-prostatectomy yet would be eligible for the addition of post-operative adjuvant radiotherapy, or;
- Salvage radiotherapy post-prostatectomy yet would be eligible for the addition of ADT.

The following criteria must also be met for coverage:

- The assay is performed on formalin-fixed paraffin embedded (FFPE) prostate biopsy tissue with at least 0.5 mm of linear tumor diameter or FFPE tissue from a prostate resection specimen, and;
- Result will be used to determine treatment according to established practice guidelines, and;
- **Patient has not received pelvic radiation or ADT prior to the biopsy or prostate resection specimen, and;**
- **Patient is monitored for disease progression according to established standards of care.**

INTENSIFICATION ELIGIBILITY FOR TREATMENT CONSIDERED

Treatment Considered	Definition	These Patients are Also Eligible For Treatment Intensification With (at least):
Conservative Management	Active surveillance or observation with PSA monitoring	RP, EBRT, or brachytherapy
Definitive Therapy (EBRT & RP)	External beam radiation therapy (EBRT) and radical prostatectomy (RP)	EBRT with a brachytherapy boost, or EBRT with the addition of short-term ADT
Definitive Therapy (EBRT) + Systemic Therapy (STADT)	EBRT with the addition of short-term androgen deprivation therapy (ADT)	EBRT with the addition of long-term ADT
Definitive Therapy (EBRT) + Systemic Therapy (LTADT)	EBRT with the addition of long-term (also known as standard) ADT	EBRT with the addition of long-term ADT and a next-generation androgen signaling inhibitor, or EBRT with the addition of long-term ADT and docetaxel chemotherapy
Observation	Observation post-prostatectomy with PSA monitoring	Post-operative adjuvant radiotherapy
Salvage Radiotherapy	Radiotherapy for patients with rising (recurrent) or persistently elevated PSA	Salvage radiotherapy with the addition of ADT

veracyte®

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