

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) <input type="checkbox"/> C61 MALIGNANT NEOPLASIA OF PROSTATE <input type="checkbox"/> R97.20 ELEVATED PSA <input type="checkbox"/> D07.5 CA IN SITU PROSTATE <input type="checkbox"/> Other _____	Bill Type <input type="checkbox"/> Insurance <input type="checkbox"/> Self-Pay <input type="checkbox"/> Medicare - Part B <input type="checkbox"/> Client Bill	Secondary Insurance? <input type="checkbox"/> Yes <input type="checkbox"/> No	Patient Status (for Medicare patients) <input type="checkbox"/> Outpatient <input type="checkbox"/> Hospital Inpatient - Date of Discharge _____
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DECIPHER TESTING. Select Decipher Prostate Biopsy OR Decipher Prostate RP.

Decipher Prostate Biopsy
See reverse side for test description.

Most Recent PSA (ng/mL)	Clinical Stage (Select one) <input type="checkbox"/> T1c <input type="checkbox"/> T2a <input type="checkbox"/> T2b <input type="checkbox"/> T2c <input type="checkbox"/> Other _____	Date of Biopsy (MM/DD/YYYY)
Evidence of Distant Metastasis? <input type="checkbox"/> Yes <input type="checkbox"/> No	Radiation or Hormone Therapy Prior to Biopsy? <input type="checkbox"/> Yes <input type="checkbox"/> No	

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? <input type="checkbox"/> Yes <input type="checkbox"/> No
Evidence of Distant Metastasis? <input type="checkbox"/> Yes <input type="checkbox"/> No		Clinical Information (select all that apply) <input type="checkbox"/> Positive Surgical Margins <input type="checkbox"/> Extraprostatic Extension <input type="checkbox"/> Seminal Vesicle Invasion <input type="checkbox"/> Bladder Neck Invasion <input type="checkbox"/> Rising PSA / Biochemical Recurrence	

PHYSICIAN SIGNATURE AND LETTER OF MEDICAL NECESSITY

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)

Decipher Prostate Biopsy		Decipher Prostate RP		
<input type="checkbox"/> Conservative Management	<input type="checkbox"/> Definitive Therapy (EBRT & RP)	<input type="checkbox"/> Definitive (EBRT) + Systemic Therapy (STADT & LTADT)	<input type="checkbox"/> Observation	<input type="checkbox"/> Salvage Radiotherapy

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 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, 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)
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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 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	



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 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 L38292

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

