

# Decipher® Bladder

Genomic Classifier

DECIPHER BLADDER 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
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/> Other _____

### BILLING INFORMATION

ICD-10 Primary Diagnosis Code(s) <input type="checkbox"/> C67.0 <input type="checkbox"/> C67.1 <input type="checkbox"/> C67.2 <input type="checkbox"/> C67.3 <input type="checkbox"/> C67.4 <input type="checkbox"/> C67.5 <input type="checkbox"/> C67.6 <input type="checkbox"/> C67.7 <input type="checkbox"/> C67.8 <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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### CLINICAL UTILITY INFORMATION

Has the patient received any of the following prior to this TURBT? (Check all that apply) <input type="checkbox"/> Newly diagnosed (no treatment received) <input type="checkbox"/> BCG, if yes please indicate the # of inductions _____ <input type="checkbox"/> Pembrolizumab	Intended Therapy (Check All That Apply) <input type="checkbox"/> BCG <input type="checkbox"/> Intravesical Chemotherapy <input type="checkbox"/> Checkpoint Inhibitor (i.e., pembrolizumab, atezolizumab, etc...) <input type="checkbox"/> Neoadjuvant Chemo + Radical Cystectomy <input type="checkbox"/> Radical Cystectomy <input type="checkbox"/> Chemoradiation <input type="checkbox"/> Other (i.e., partial cystectomy, radiation therapy, etc....) _____
What was the patient's stage at initial diagnosis? <input type="checkbox"/> Ta Low Grade <input type="checkbox"/> Ta High Grade <input type="checkbox"/> Tis <input type="checkbox"/> T1 Low Grade <input type="checkbox"/> T1 High Grade <input type="checkbox"/> T2-T4	

### DECIPHER TESTING

<input type="checkbox"/> <b>Decipher Bladder</b> See reverse side for test description.			
Specimen Type <input type="checkbox"/> TURBT Note: sample sent must be initial TURBT taken prior to chemo or radiation therapy	Date of TURBT (MM/DD/YYYY)	Histology Type <input type="checkbox"/> Urothelial Carcinoma	Is the patient's regional lymph node status N2 or N3? <input type="checkbox"/> Yes <input type="checkbox"/> No
Tumor Type Non-Muscle Invasive Carcinoma <input type="checkbox"/> High Grade cT1 Muscle Invasive Carcinoma <input type="checkbox"/> cT2 <input type="checkbox"/> cT3 <input type="checkbox"/> cT4a	Prior Radiation Therapy? <input type="checkbox"/> Yes <input type="checkbox"/> No	Prior Systemic Chemotherapy? <input type="checkbox"/> Yes <input type="checkbox"/> No	Evidence of Distant Metastasis? <input type="checkbox"/> Yes <input type="checkbox"/> No

### PHYSICIAN SIGNATURE AND LETTER OF MEDICAL NECESSITY

I confirm that this test is medically necessary, that I am the treating physician, and that the results will be used for treatment decisions and medical management for the patient. Decipher helps me and the patient determine the best management plan for their bladder cancer among multiple potential treatments which have varied or increasing levels of intensity based on consensus guidelines. 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. 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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### 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	

### THE FOLLOWING MUST BE ATTACHED

- Demographic/face sheet
- Most recent office note
- Pathology report
- Copy of insurance card(s), if applicable



Veracyte Labs SD

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## DECIPHER BLADDER TEST DESCRIPTION

Decipher Bladder Genomic Subtyping Classifier (GSC) uses an oligonucleotide microarray to measure 219 genes to determine the probability of a patient tumor sample belonging to each of five molecular subtypes (Luminal, Luminal Infiltrated, Basal, Basal Claudin-Low, and Neuroendocrine-Like) based on functional molecular pathways. The tumor samples are classified as belonging to the subtype with the highest calculated probability.

Decipher Bladder GSC is intended for use in patients with American Joint Committee on Cancer (AJCC) Stage I to IIIA bladder cancer who are candidates for definitive local therapy such as chemotherapy, radical cystectomy, or chemoradiation, and have not yet received pelvic radiation or chemotherapy for treatment of bladder cancer. Results are intended for use as an adjunct to conventional clinical variables and nomograms currently used in determining treatment for these patients. Decipher Bladder is billed using CPT 0016M.

This test was developed and its performance characteristics determined by Veracyte Labs SD. The laboratory is regulated under CLIA '88 as qualified to perform high complexity clinical testing. This test has not been cleared or approved by the FDA. This test is used for clinical purposes and clinical correlation of its results are recommended. It should not be regarded as investigational or for research.

## ORDER ACCEPTANCE CRITERIA

Orders submitted for Decipher Bladder testing must meet the criteria below.

- Specimen Type: TURBT (Trans-Urethral Resection of Bladder Tumor)
- Tumor Stage: AJCC Stage I to IIIA (T1-T4a, N0 or N1, M0; If T1, high grade)
- Primary Histology Type: Urothelial Carcinoma
- No evidence of distant metastasis
- No prior chemotherapy
- No prior radiation therapy

## MEDICARE INDICATIONS FOR DECIPHER BLADDER

Medicare Beneficiaries Eligibility - LCD L38647

Coverage Indications, Limitations, and/or Medical Necessity

This contractor will cover molecular diagnostic tests for use in a beneficiary with bladder cancer when all of the following conditions are met:

1. The beneficiary is being actively managed for bladder cancer.
2. The beneficiary is within the population and has the indication for which the test was developed and is covered. The lab providing the test is responsible for clearly indicating to treating clinicians the population and indication for test use.
3. At least 1 of the 2 criteria are met:
  - a. The patient is a candidate for multiple potential treatments, which could be considered to have varied or increasing levels of intensity based on a consensus guideline, and the physician and patient must decide among these treatments. OR
  - b. The patient is a candidate for multiple therapies, and the test has shown that it predicts response to specific therapy among accepted therapy options based on nationally recognized consensus guidelines.
4. The test demonstrates analytical validity including both analytical and clinical validations. If the test relies on an algorithm (which may range in complexity from a threshold determination of a single numeric value to a complex mathematical or computational function), the algorithm must be validated in a cohort that is not a development cohort for the algorithm.
5. The test has demonstrated clinical validity and utility, establishing a clear and significant biological/molecular basis for stratifying patients and subsequently selecting (either positively or negatively) a clinical management decision (in 4. above) in a clearly defined population.
6. The test successfully completes a Molecular Diagnostic Program (MolDX<sup>®</sup>) technical assessment that ensures the test is reasonable and necessary as described in 4 and 5 above.

NOTE: Decipher Bladder meets the above criteria and is covered for Medicare beneficiaries per Billing and Coding Article A58181.



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