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			
DOB (MM/DD/YYYY)	Sex ☐ M ☐ F	Patient Medical Record #	Race / Ethnicity

ORDERING PHYSICIAN INFORMATION

Account #	Office / Practice / Institution Name
Address	
Telephone	Fax
☐	☐
☐	☐
☐	☐ Other_____

BILLING INFORMATION

ICD-10 Primary Diagnosis Code(s)	Bill Type	Secondary Insurance?	Patient Status (for Medicare patients)
☐ C67.0 ☐ C67.1 ☐ C67.2 ☐ C67.3 ☐ C67.4 ☐ C67.5 ☐ C67.6 ☐ C67.7 ☐ C67.8 ☐ Other_____	☐ Insurance ☐ Self-Pay ☐ Medicare - Part B ☐ Client Bill	☐ Yes ☐ No	☐ Outpatient ☐ Hospital Inpatient - Date of Discharge _____

CLINICAL UTILITY INFORMATION

Has the patient received any of the following prior to this TURBT? (Check all that apply)	Intended Therapy (Check All That Apply)
☐ Newly diagnosed (no treatment received) ☐ BCG, if yes please indicate the # of inductions_____ ☐ Pembrolizumab	☐ BCG ☐ Intravesical Chemotherapy ☐ Checkpoint Inhibitor (i.e., pembrolizumab, atezolizumab, etc...) ☐ Neoadjuvant Chemo + Radical Cystectomy ☐ Radical Cystectomy ☐ Chemoradiation ☐ Other (i.e., partial cystectomy, radiation therapy, etc....) _____

What was the patient's stage at initial diagnosis?
☐ Ta Low Grade ☐ Ta High Grade ☐ Tis ☐ T1 Low Grade ☐ T1 High Grade ☐ T2-T4

DECIPHER TESTING

☐ **Decipher Bladder**
See reverse side for test description.

Specimen Type	Date of TURBT (MM/DD/YYYY)	Histology Type	Is the patient's regional lymph node status N2 or N3?
☐ TURBT Note: sample sent must be initial TURBT taken prior to chemo or radiation therapy		☐ Urothelial Carcinoma	☐ Yes ☐ No
Tumor Type Non-Muscle Invasive Carcinoma ☐ High Grade cT1 Muscle Invasive Carcinoma ☐ cT2 ☐ cT3 ☐ cT4a	**Prior Radiation Therapy?** ☐ Yes ☐ No	**Prior Systemic Chemotherapy?** ☐ Yes ☐ No	**Evidence of Distant Metastasis?** ☐ Yes ☐ 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)

THE FOLLOWING MUST BE ATTACHED

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

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

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 determing 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®) 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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