DECIPHER BY GENOMEDX

Please print, sign and fax to: GenomeDx at
1-855-324-2768
or email to:
customersupport@genomedx.com

ADVERSE EVENT REPORT (AER) - FORM 3

DECIPHER® CERTIFICATION AND TRAINING REGISTRY (DECIPHER CTR)

Date: _____

Patient's Name: _____ **Date of Birth:** _____

Physician's Name: _____

Physician's Address: _____ **City:** _____ **State:** ____ **Zip:** _____

Local Coverage Decision (LCD) L36343 requires that healthcare providers who are registered in the Decipher Prostate Cancer Classifier Certification and Training Registry (Decipher Prostate Cancer Classifier CTR) collect and report data to CMS MolDx contractor on those Medicare patients tested under the Decipher Prostate Cancer Classifier CTR.

This Adverse Event Report form is provided in order to capture undesirable experiences of a serious nature that occur to a Medicare patient being followed in the Decipher CTR.

GenomeDx has agreed to receive these reports for the purpose of reporting to CMS MolDx contractor on your behalf in compliance with the LCD. To protect the confidentiality of protected health information (PHI), all data collected will be de-identified and aggregated for reporting to CMS MolDx contractor. If you have any questions, you may contact GenomeDx Customer Service at the number above.

Decipher Accession #: _____ **Patient Age:** ____ **Date of Last Follow up:** _____

1. Decipher Score:

- ○ Genomic High Risk
- ○ Genomic Average Risk
- ○ Genomic Low Risk

2. Evidence of Disease progression, if any:

- ☐ Biochemical Failure
- ☐ Local Recurrence
- ☐ Development of Metastasis
- ☐ Other _____
- ☐ Prostate Cancer-Specific Death
- ☐ Non-Prostate Cancer Related Death
- ☐ N/A, No Evidence of Disease Progression

a. On what date was the adverse event diagnosed? _____

b. What interventions were performed in response, if any (include date of intervention)?

- ☐ Radiation Therapy, Date: _____
- ☐ Androgen Deprivation Therapy, Date: _____
- ☐ Secondary Hormonal Manipulation, Date: _____
- ☐ Additional Hormonal Manipulation, Date: _____
- ☐ Other Systemic Therapy (Sipuleucel, Taxotere), Date: _____
- ☐ Other Chemotherapy, Date: _____
- ☐ Other: _____

To the best of my knowledge, the information above is accurate.

Healthcare Provider Signature: _____ Date: _____

Healthcare Provider Name (please print): _____ NPI #: _____

Healthcare Provider Name Phone Number: _____ Email: _____