FOUNDATION MEDICINE®

TEST REQUISITION FORM & STATEMENT OF MEDICAL NECESSITY

For Foundation Medicine (FMI) Use Only

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IF REQUIRED FIELDS MARKED WITH AN * ASTERISK ARE NOT PROVIDED, TESTING MAY BE DELAYED.

1. PATIENT INFORMATION *(*Indicates a required field)*

*First Name *(legal name)*	MI *(optional)*	*Last Name *(legal name)*		
*DOB (MM/DD/YYYY)	*Genetic Sex ☐ M ☐ F	Medical Record # *(optional)*	*Primary Phone	
*Address	*City	*State	*Postal Code	*Country

2. CURRENT DIAGNOSIS & PATIENT HISTORY *(*Indicates a required field)*

*Primary ICD-10 *(C&D codes only, see section 10)*	*Stage	*Diagnosis: ☐ Breast ☐ NSCLC ☐ Ovarian ☐ Prostate ☐ Colorectal ☐ Melanoma ☐ Other:	*Disease status at time of testing *(select all that apply)*: ☐ Metastatic ☐ Recurrent ☐ Relapsed ☐ Refractory ☐ Unresectable ☐ None of these options

*Date of Original Diagnosis *(MM/DD/YYYY)*	*Has the patient failed prior treatments? ☐ Yes ☐ No	*Prior or Current Treatments: ☐ None ☐ Targeted Therapy ☐ Immunotherapy ☐ Chemotherapy ☐ Combo Therapy	The patient is seeking further treatment and is: ☐ Newly diagnosed (Stage III/IV) ☐ Not responding to therapy	*Has this tumor been tested by Foundation Medicine previously? ☐ Yes ☐ No *If yes above, has the disease progressed? ☐ Yes ☐ No

Attachments:	Are there any satisfactory alternative treatment options available for the patient which do not require genomic testing? ☐ Yes ☐ No	*Has the patient received a transplant? ☐ Yes ☐ No
☐ Copy of recent pathology/cytology reports, including (if available) CBC/differential, BMA differential, FAB classification. ☐ Results from other testing by FISH, IHC, PCR, NGS, or other methodologies (including ER, PR, HER2, EGFR, KRAS, etc.)		

3. BILLING INFORMATION *(*Indicates a required field)*

*Bill Type

☐	**Medicare – Part B**	☐ ABN attached if required *(see page 3 for criteria)*	*Medicare Policy ID	*Patient Status at time of specimen collection *(for Medicare patients)*: ☐ Hospital Inpatient *(provide discharge date to right)* ☐ Hospital Outpatient ☐ Office (Non-Hospital) ☐ Not yet discharged		Discharge Date *(MM/DD/YYYY)*
☐	**Insurance or Medicare Advantage** *(attach copy of card)*	*Plan Name	*Policy #	Group # *(optional)*	Prior Authorization # *(optional)*	
☐	**Self-Pay/Uninsured**	*Is Self-Pay contact info the same as patient contact info above? ☐ Yes ☐ No *(provide contact info to right)*	*Contact name	*Phone	*Email	
☐	**Hospital/Institution**	Is hospital/institution bill info the same as facility address that will be provided below? ☐ Yes ☐ No *(provide address to right)*	*Address	*City	*State	*Postal Code

4. TREATING PHYSICIAN INFORMATION *(*Indicates a required field)*

*Treating Physician (full legal name)	*Facility Name	Foundation Medicine Account # *(optional)*		
*Facility Address	*City	*State	*Postal Code	*Country
*Email		*Phone		Fax *(optional)*
Additional Physician to be Copied *(optional)*	Facility Name *(optional)*	Email *(preferred)*	Phone *(optional)*	Fax *(optional)*

*Is the facility a hospital, hospital outpatient department, critical access hospital, or ambulatory surgical center? *(see page 3)* ☐ Yes ☐ No

*If yes, what is the facility's network status with the patient's insurance plan? ☐ In-network ☐ Out-of-network ☐ Unknown

5. TEST SELECTION & SPECIMEN PROCUREMENT *(*Indicates a required field)*

*Genomic Test/Test Combination	Accepted Specimen Types	*Specimen Procurement Method	*Additional Options (see section 10 for additional information on reflex testing.)
☐ **FoundationOne®CDx** ☐ **FoundationOne®CDx + FoundationOne®RNA**	**FFPE TISSUE** *(for optimal processing please send tissue block)*	☐ **Physician Procurement:** Physician will arrange FFPE block/Unstained slides specimen shipment ☐ **FMI Procurement:** Requesting Foundation Medicine procurement services *(please fill out section 6)*	☐ If tissue submitted does not meet the criteria for successful FoundationOne CDx testing, **reflex** to FoundationOne Liquid CDx. ↳ Check One: ☐ Physician will arrange blood specimen collection ☐ Request Foundation Medicine mobile phlebotomy services
☐ **FoundationOne®Liquid CDx**	**PERIPHERAL WHOLE BLOOD**	☐ **Physician Procurement:** Physician will arrange blood specimen collection ☐ **FMI Procurement:** Requesting Foundation Medicine mobile phlebotomy services	☐ If blood sample submitted does not meet the criteria for successful testing, **reflex** to FoundationOne®CDx. ↳ Check One: ☐ Physician will arrange Block/Slides specimen shipment ☐ Requesting Foundation Medicine procurement services *(please fill out section 6)*
☐ **FoundationOne®Heme**	**PERIPHERAL WHOLE BLOOD, BONE MARROW ASPIRATE, OR FFPE TISSUE**	☐ **Physician Procurement:** Physician will arrange for specimen shipment ☐ **FMI Procurement:** Requesting Foundation Medicine mobile phlebotomy (blood), or procurement services (please fill out section 6)	Specimen has or is undergoing other NGS testing? ☐ Yes ☐ No

Add on testing & services (optional)	*Accepted Specimen Types*	*Specify preferred test:* When ordering multiple tests, please ensure that an FFPE block or unstained slides are provided *(see specimen instructions). (please fill out section 6 for FMI procurement services)*
☐ **IHC Testing**	**FFPE TISSUE** *(for optimal processing, please send tissue block)*	☐ PD-L1 22C3 ☐ PD-L1 28-8 ☐ PD-L1 SP142 ☐ PD-L1 SP263 ☐ FOLR1 ☐ CLDN18 ☐ HER2 (with ISH reflex)† ☐ MET ☐ MMR panel
☐ **Cancer of Unknown Primary (CUP)** *Molecular pathologist interpretation*	*For cancers of unknown primary, difficult differential diagnoses, or specific molecular pathology queries.* Molecular pathologist-led consultation, available with any test, using the Foundation Medicine CGP platform's advanced genomic biomarkers for molecularly-guided diagnosis; provided as a matter of course or upon request. **Please attach relevant clinical, pathologic, or radiologic data, if available.**	

† For a HER2 IHC score of 2+ in breast and gastroesophageal carcinoma, in situ hybridization testing is performed per professional society guidelines.

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6. PATHOLOGY LABORATORY & PROCUREMENT SERVICES *(*Indicates a required field if applicable to test order)*

*Pathology Lab Name		Submitting Pathologist Name *(optional)*
*Phone	Email *(preferred)*	Fax *(if email not provided)*
*Specimen Retrieval Type ☐ Physician is requesting a specific specimen (add specimen details below) ☐ Physician is requesting the Pathologist to choose specimen		
*Specimen ID	*Date of Collection (MM/DD/YYYY)	*Specimen (biopsy) Site
*Alternate Specimen ID	*Date of Collection (MM/DD/YYYY)	*Alternate Specimen (biopsy) Site

7. FFPE BLOCK RETURN INFORMATION
*(*Indicates a required field if applicable to test order)*

*Return Address			
*City	*State	*Postal Code	*Country
Email *(preferred)*	Phone *(optional)*	Fax *(optional)*	

8. RELEVANT CLINICAL HISTORY
(All Required For Medical Coverage Determination)

a. Is a tissue specimen from a recent procedure available?	☐ Yes ☐ No
b. Tissue specimen is insufficient for testing or tissue testing resulted as a Quantity Not Sufficient (QNS)	☐ Yes ☐ No
c. Is the requested test assessing for tumor mutation burden (TMB) to identify if the patient is a candidate for checkpoint inhibitor immunotherapy?	☐ Yes ☐ No

9. FDA COMPANION DIAGNOSTIC INDICATIONS[1] FOR FOUNDATIONONE CDX AND FOUNDATIONONE LIQUID CDX* *(*Required Section: Select or write in indication for testing)*

	TUMOR TYPES	BIOMARKERS[2] *(See complete gene list on our website)*	FDA-APPROVED THERAPY[3] *Last Updated 10/25/2023, please use "If other" box below to include additional*
☐	**Solid tumors**	TMB ≥ 10 mutations per megabase	Keytruda® (pembrolizumab)
		NTRK1/2/3 fusions	Vitrakvi® (larotrectinib) or Rozlytrek® (entrectinib)
		MSI-H	Keytruda® (pembrolizumab)
		RET	Retevmo (selpercatinib)
☐	**Non-Small Cell Lung Cancer (NSCLC)**	*EGFR* exon 19 deletions and *EGFR* exon 21 L858R alterations	*EGFR* Tyrosine Kinase Inhibitors (TKI) approved by FDA[1]
		EGFR exon 20 T790M alterations	Tagrisso® (osimertinib)
		ALK rearrangements	Alecensa®(alectinib), Alunbrig® (brigatinib), Xalkori® (crizotinib), or Zykadia® (ceritinib)
		MET single nucleotide variants (SNVs) and indels that lead to MET exon 14 skipping	Tabrecta® (capmatinib)
		BRAF V600E	Tafinlar® (dabrafenib) in combination with Mekinist® (trametinib) or BRAFTOVI® (encorafenib) in combination with MEKTOVI® (binimetinib)
		EGFR exon 20 insertion mutations	EXKIVITY® (mobocertinib)
		ROS1 fusions	Rozlytrek® (entrectinib)
☐	**Melanoma**	*BRAF* V600E	*BRAF* Inhibitors approved by FDA*
		BRAF V600E and V600K	Mekinist® (trametinib) or BRAF/MEK Inhibitor Combinations approved by FDA[1]
		BRAF V600 mutation-positive	Tecentriq® (atezolizumab) in combination with Cotellic® (cobimetinib) and Zelboraf® (vemurafenib)
☐	**Breast Cancer**	*ERBB2* (HER2) amplification	Herceptin® (trastuzumab), Kadcyla® (ado-trastuzumab-emtansine), or Perjeta® (pertuzumab)
		PIK3CA C420R, E542K, E545A, E545D [1635G>T only], E545G, E545K, Q546E, Q546R, H1047L, H1047R, and H1047Y alterations	Piqray® (alpelisib)
☐	**Colorectal Cancer**	*KRAS* wild-type (absence of mutations in codons 12 and 13)	Erbitux® (cetuximab)
		KRAS wild-type (absence of mutations in exons 2, 3 and 4) and *NRAS* wild-type (absence of mutations in exons 2, 3 and 4)	Vectibix® (panitumumab)
		BRAF V600E	BRAFTOVI® (encorafenib) in combination with cetuximab
☐	**Ovarian Cancer**	*BRCA1/2* alterations	Lynparza® (olaparib)
☐	**Cholangiocarcinoma**	*FGFR2* fusions and select rearrangements	Pemazyre™ (pemigatinib) or Truseltiq™ (infigratinib)
☐	**Prostate Cancer**	Homologous Recombination Repair (*HRR*) gene (*BRCA1, BRCA2, ATM, BARD1, BRIP1, CDK12, CHEK1, CHEK2, FANCL, PALB2, RAD51B, RAD51C, RAD51D* and *RAD54L*) alterations	Lynparza® (olaparib)
		BRCA1/2 alterations	Rubraca® (rucaparib) or AKEEGA® (niraparib and abiraterone acetate dual action tablet)
☐	**If other indications for testing apply, please indicate here:**		

10. OTHER INFORMATION

For information on ICD codes, visit this website: *https://icd10cmtool.cdc.gov/*

PORTFOLIO REFLEX OPTION:
If the reflex option is selected, we will proceed with the initial NGS test selected and if the specimen does not meet the criteria for successful testing, we will automatically reflex to the other test (in Section 5) and procure a new specimen. The failed test is not billed, and the successful test will be billed according to our standard practices. Please see foundationmedicine.com/order for more information.

11. PHYSICIAN CERTIFICATION OF MEDICAL NECESSITY AND CONSENT *(*Indicates a required field)*

My signature below certifies that **(1)** I am the patient's treating physician and am authorized under applicable law to order the tests on this test requisition, **(2)** each test ordered on this test requisition is medically necessary for the patient, **(3)** the patient has decided to seek further cancer treatment, **(4)** the results of each test will inform the patient's ongoing treatment plan, **(5)** I have explained to the patient* the nature and purpose of each test to be performed pursuant to this test requisition, and the patient* has had the opportunity to ask questions regarding each test and the collection, use, and disclosure of his/her samples and data, **(6)** I have obtained informed consent from the patient* using the consent form available at *https://foundationmedicine.com/asset/patient-consent* to have each test performed, including the collection, use, and disclosure of his/her samples and data, and **(7)** I have informed the patient* that he/she may receive a copy of the signed consent and have also included a signed copy in his/her medical record. I understand that Foundation Medicine may reach out to me to request a copy of the signed consent, in which case I will furnish Foundation Medicine a signed copy of the consent. * (or the patient's legal guardian or representative)

In addition, I certify that, if ordering concurrent tissue and blood-based comprehensive genomic profiling, this order will assist me in treating my patient and is medically necessary based on several clinical factors, which may include, but are not limited to: the tissue is at risk to fail (e.g., small tissue, archived tissue); acknowledgement that the site of tissue sampling may not be reflective of all sites of disease in the patient; without concurrent testing I may not have a timely result to make a treatment decision, among others.

***Treating Physician Signature**	***Printed Full Name** (Full legal name)	***Date** (MM/DD/YYYY)

Notice for CA HCPs: Please review our privacy policy, available at *https://www.foundationmedicine.com/california-privacy-notice*, for more information about how we collect, use and disclose personal information about ordering physicians.

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TECHNICAL INFORMATION

→ **Visit Our Testing Portfolio Here:** *https://www.foundationmedicine.com/portfolio*

FOUNDATION**ONE**®**CDx**

FoundationOne®CDx is a qualitative next-generation sequencing based *in vitro* diagnostic test for advanced cancer patients with solid tumors and is for prescription use only. The test analyzes 324 genes as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB) and is a companion diagnostic to identify patients who may benefit from treatment with specific therapies in accordance with the approved therapeutic product labeling. Additional genomic findings may be reported and are not prescriptive or conclusive for labeled use of any specific therapeutic product. Use of the test does not guarantee a patient will be matched to a treatment. A negative result does not rule out the presence of an alteration. Some patients may require a biopsy. For the complete label, including companion diagnostic indications and important risk information, please visit *www.F1CDxLabel.com*

FOUNDATION**ONE**®**RNA**

FoundationOne®RNA is a laboratory developed test that was developed and its performance characteristics determined by Foundation Medicine. FoundationOne RNA has not been cleared or approved by the U.S. Food and Drug Administration. FoundationOne RNA is a test for solid tumors which utilizes RNA sequencing to interrogate 318 cancer-related genes to capture gene fusions and rearrangements. A negative result does not rule out the presence of an alteration. Genomic findings are not prescriptive or conclusive for labeled use of any specific therapeutic product.

FOUNDATION**ONE**®**LIQUID CDx**

FoundationOne®Liquid CDx is for prescription use only and is a qualitative next-generation sequencing based *in vitro* diagnostic test for advanced cancer patients with solid tumors. The test analyzes 324 genes utilizing circulating cell-free DNA and is FDA-approved to report short variants in 311 genes and as a companion diagnostic to identify patients who may benefit from treatment with specific therapies (listed in Table 1 of the Intended Use) in accordance with the approved therapeutic product labeling. Additional genomic findings may be reported and are not prescriptive or conclusive for labeled use of any specific therapeutic product. Use of the test does not guarantee a patient will be matched to a treatment. A negative result does not rule out the presence of an alteration. Patients who are negative for companion diagnostic mutations should be reflexed to tumor tissue testing and mutation status confirmed using an FDA-approved tumor tissue test, if feasible. For the complete label, including companion diagnostic indications and complete risk information, please visit *www.F1LCDxLabel.com*

FOUNDATION**ONE**®**HEME**

FoundationOne®Heme is a qualitative next-generation sequencing based laboratory developed test (LDT) for detection of substitutions, insertion and deletion alterations (indels), copy number alterations (CNAs), select gene rearrangements, and genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB). FoundationOne Heme uses DNA and RNA isolated from formalin-fixed, paraffin-embedded (FFPE) tumor specimens, as well as from peripheral blood (PB), bone marrow aspirate (BMA) specimens and cytology smear specimens. FoundationOne Heme is intended to provide cancer genomic mutation profiling to be used by qualified health care professionals in accordance with professional guidelines in oncology for patients with hematologic neoplasms and solid tumors. Genomic findings are not prescriptive or conclusive for labeled use of any specific therapeutic product.

IHC Testing

Scoring and clone utilization for IHC testing is based on FDA-approved indications. Refer to *https://www.foundationmedicine.com/info/detail/ihc-testing* for more information.

CERTIFICATION AND ACCREDITATION

https://www.foundationmedicine.com/resource/licenses

FACILITY INFORMATION

This information will be used by Foundation Medicine to determine if the test(s) performed may result in a bill that is affected by surprise billing laws.

MEDICARE COVERAGE SUMMARY *(Foundation Medicine tests may be covered by Original Medicare[4] and Medicare Advantage[5])*

TEST	CONDITIONS FOR MEDICARE COVERAGE	PATIENT COVERAGE CRITERIA
FoundationOne®CDx	Covered[6] if all patient coverage criteria are met. ABN required for an Original Medicare beneficiary if they do not meet the patient coverage criteria or if person ordering the test is not a treating physician[7].	i) Patient has been diagnosed with a solid malignant neoplasm; *AND* ii) Patient has either recurrent, relapsed, refractory, metastatic, or advanced stage III or IV cancer (only requires one of these to be met); *AND* iii) Patient has not been previously tested with the same test using NGS for the same cancer genetic content[9]; *AND* iv) Patient has decided to seek further cancer treatment (e.g., therapeutic chemotherapy)
FoundationOne®Liquid CDx		
FoundationOne®RNA	Covered[10] if all patient coverage criteria are met. ABN required for an Original Medicare beneficiary if they do not meet the patient coverage criteria or if person ordering the test is not a treating physician[7].	
FoundationOne®Heme	Covered[8] if all patient coverage criteria are met. ABN required for an Original Medicare beneficiary if they do not meet the patient coverage criteria or if person ordering the test is not a treating physician[7].	i) Patient has been diagnosed with acute myeloid leukemia (AML), myelodysplastic syndrome (MDS) or myeloproliferative neoplasms (MPN); *OR* ii) Patient has a suspected myeloid malignancy with an undefined cytopenia for greater than 4 months, and other possible causes have been reasonably excluded *AND (both criteria iii and iv below)* iii) Patient has not previously received or is not currently receiving NGS testing on the specimen for which the test is currently being ordered iv) Patient has not been tested with the same test for the same genetic content[9]

References

1. For the most current information about the therapeutic products in this group, go to: https://www.fda.gov/medical-devices/in-vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-in-vitro-and-imaging-tools
2. Please reference the US Food & Drug Administration website for a current list of cleared or approved companion diagnostic devices and associated therapies: https://www.fda.gov/medical-devices/in-vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-in-vitro-and-imaging-tools
3. Inclusive of the targeted therapies listed and others for which FoundationOne CDx and/or FoundationOne Liquid CDx may be an FDA-approved companion diagnostic in the future
4. Medicare administered by federal government.
5. Medicare administered by private insurers.
6. Decision Memo for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450R – reference appendix B).
7. A "treating physician" is a physician, as defined in §1861(r) of the Social Security Act, who furnishes a consultation or treats a beneficiary for a specific medical problem, and who uses the results of a diagnostic test in the management of the beneficiary's specific medical problem. More information is available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R80BP.pdf*.
8. MolDx Local Coverage Determination (LCD): Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies (L38047).
9. Repeat testing (FoundationOne®CDx, FoundationOne®Liquid CDx, or FoundationOne®Heme) after disease progression (i.e., there is evidence of a new malignant growth despite response to a prior targeted therapy) or for additional primary cancer diagnosis may be covered under the NCD for qualifying Medicare beneficiaries.
10. NGS Local Coverage Determination (LCD): Genomic Sequence Analysis Panels in the Treatment of Solid Organ Neoplasms (L37810)

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