FOUNDATIONONE®CDx

324 Genes
25+ Companion Diagnostic Claims
1 FDA-Approved Tissue Test

DEMONSTRATED CLINICAL OUTCOMES DATA

Companion diagnostic claims across multiple targeted therapies and cancer indications

The first FDA-approved tissue-based broad companion diagnostic for all solid tumors, FoundationOne®CDx analyzes guideline-recommended genes to help inform more treatment options for advanced cancer patients.

Save Time and Tissue with One Comprehensive Panel

A single test **analyzes 324 genes** and provides comprehensive results **typically within 12 days*** to help inform treatment strategies.

Includes results from genomic signatures:

- Tumor Mutational Burden (TMB)
- Microsatellite Instability (MSI)
- Loss of heterozygosity (LOH)†

* From receipt of specimen and complete order
† LOH reported for ovarian cancer only

Identify More Treatment Options

Help predict patient benefit to **25+** targeted therapies across **7+** cancer types with **the most companion diagnostic claims of any comprehensive genomic profiling test on the market.**[1]

Actionable Insights

92% of patients

received a **FoundationOne CDx** report with a recommended therapy in their tumor type, a recommended therapy in another tumor type, or a clinical trial option.[4]

Medicare Covered

Coverage and Patient Access:

- Qualifying Original Medicare beneficiaries have no out-of-pocket costs for FoundationOne CDx.[2]
- 84% of patients have $0 financial responsibility for Foundation Medicine testing.[3]
- As part of our FoundationAccess™ program, for each comprehensive genomic profiling test ordered, we complete a benefits investigation and reach out to all patients whom we expect may have out-of-pocket costs.

FOR MORE DETAILED INFORMATION VISIT *foundationmedicine.com/F1CDx*

Companion Diagnostic Indications

TUMOR TYPES	BIOMARKERS	FDA-APPROVED THERAPY
Non-Small Cell Lung Cancer (NSCLC)	*EGFR* exon 19 deletions and *EGFR* exon 21 L858R alterations	Gilotrif® (afatinib), Iressa® (gefitinib), Tagrisso® (osimertinib) or Tarceva® (erlotinib)
	EGFR exon 20 T790M alterations	Tagrisso® (osimertinib)
	ALK rearrangements	Alecensa® (alectinib), Alunbrig® (brigatinib), Xalkori® (crizotinib), or Zykadia® (ceritinib)
	BRAF V600E	Tafinlar® (dabrafenib) in combination with Mekinist® (trametinib)
	MET single nucleotide variants (SNVs) and indels that lead to *MET* exon 14 skipping	Tabrecta™ (capmatinib)
Melanoma	*BRAF* V600E	Tafinlar® (dabrafenib) or Zelboraf® (vemurafenib)
	BRAF V600E or V600K	Mekinist® (trametinib) or Cotellic® (cobimetinib) in combination with 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 (CRC)	*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)
Ovarian Cancer	*BRCA1/2* alterations	Lynparza® (olaparib) or Rubraca® (rucaparib)
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)
Solid Tumors	TMB ≥ 10 mutations per megabase	Keytruda® (pembrolizumab)
	NTRK1/2/3 fusions	Vitrakvi® (larotrectinib)

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.

References

1. U.S. Food & Drug Administration. List of Cleared or Approved Companion Diagnostic Devices. Content current as of February 4, 2021. Accessed March 5, 2021. https://www.fda.gov/medical-devices/vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-vitro-and-imaging-tools
2. Medicare and Medicare Advantage members have coverage in accordance with the Centers for Medicare and Medicaid Services (CMS) national coverage determination (NCD) criteria.
3. Data on File, Foundation Medicine, Inc., 2021. Based on settled claims from 1/1/20 to 3/31/21 for all tests offered by Foundation Medicine and reported during that time before considering any financial assistance. 58% of commercially insured and 95% of Medicare and Medicare Advantage patients paid $0 for Foundation Medicine testing.
4. Based on US clinical tests reported between September 1, 2020 and June 1, 2021. Data current as of July, 2021. Only one sample per patient included. For patients who received multiple tests, the most recent test result was used.

FOUNDATION MEDICINE®

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