

Uncovering Treatment Options for Patients with Colorectal Cancer

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Recommend Molecular Testing in Colorectal Cancer (CRC)¹⁻²

- 1** | **RAS Mutations– *KRAS* and *NRAS*:** *RAS* mutations often confer resistance to *EGFR* therapies³
- 2** | ***BRAF* Mutations:** *BRAF* is a strong prognostic marker⁴ and may help inform the use of *BRAF*-targeted therapy
- 3** | Anti-HER2 therapy is only indicated in **HER2-amplified** tumors that are also *RAS* and *BRAF* wild type
- 4** | **MSI Status:** Testing MSI may help inform the use of immunotherapy in patients with metastatic CRC

Our portfolio of tests analyzes all guideline recommended genes and biomarkers for relevant alterations in patients with CRC including *KRAS*, *NRAS*, *BRAF*, HER2 and MSI.*



The Value of Comprehensive Genomic Profiling with Foundation Medicine:



Of the 6.4% of patients that harbor potentially resistant *KRAS* mutations outside of codons 12 and 13, **88% may not be identified by focused PCR-based testing methods** as having such a *KRAS* mutation.

Rankin et al.,
Broad Detection of Alterations...,
The Oncologist



TMB can potentially identify an additional **3% of CRC patients[†]** who are MSS (microsatellite stable) but **who may benefit from cancer immunotherapy.⁶**

[†] Based on a TMB-high cut-off of 12 mutations per megabase. Research is ongoing to determine appropriate cut-offs for colorectal and other cancer types, which could impact the number of MSS patients who are determined to have a high TMB in that disease.

Fabrizio et al.,
Beyond microsatellite testing...,
Journal of GI Oncology



Patients with rare alterations in genes such as *ALK*, *ROS1* and *NTRK*[‡] have a poorer prognosis and **may have exceptional benefit from new targeted therapies and clinical trials.⁷**

[‡] *NTRK* not currently tested on FoundationOne Liquid



Additional clinically relevant genes for CRC patients: *PIK3CA*, *PTEN*, *CTNNB1*, *APC*, *RET*, *ERBB2*, and others.

A portfolio of tests to help identify more treatment options:



FOUNDATIONONE® CDx

TISSUE BIOPSY

FoundationOne CDx is FDA-approved with Medicare coverage for qualifying Medicare patients.⁸

- Analyzes 324 genes
- Reports TMB and MSI



FOUNDATIONONE® LIQUID

LIQUID BIOPSY

FoundationOne Liquid is a laboratory developed test that delivers high-quality answers from a simple blood draw.

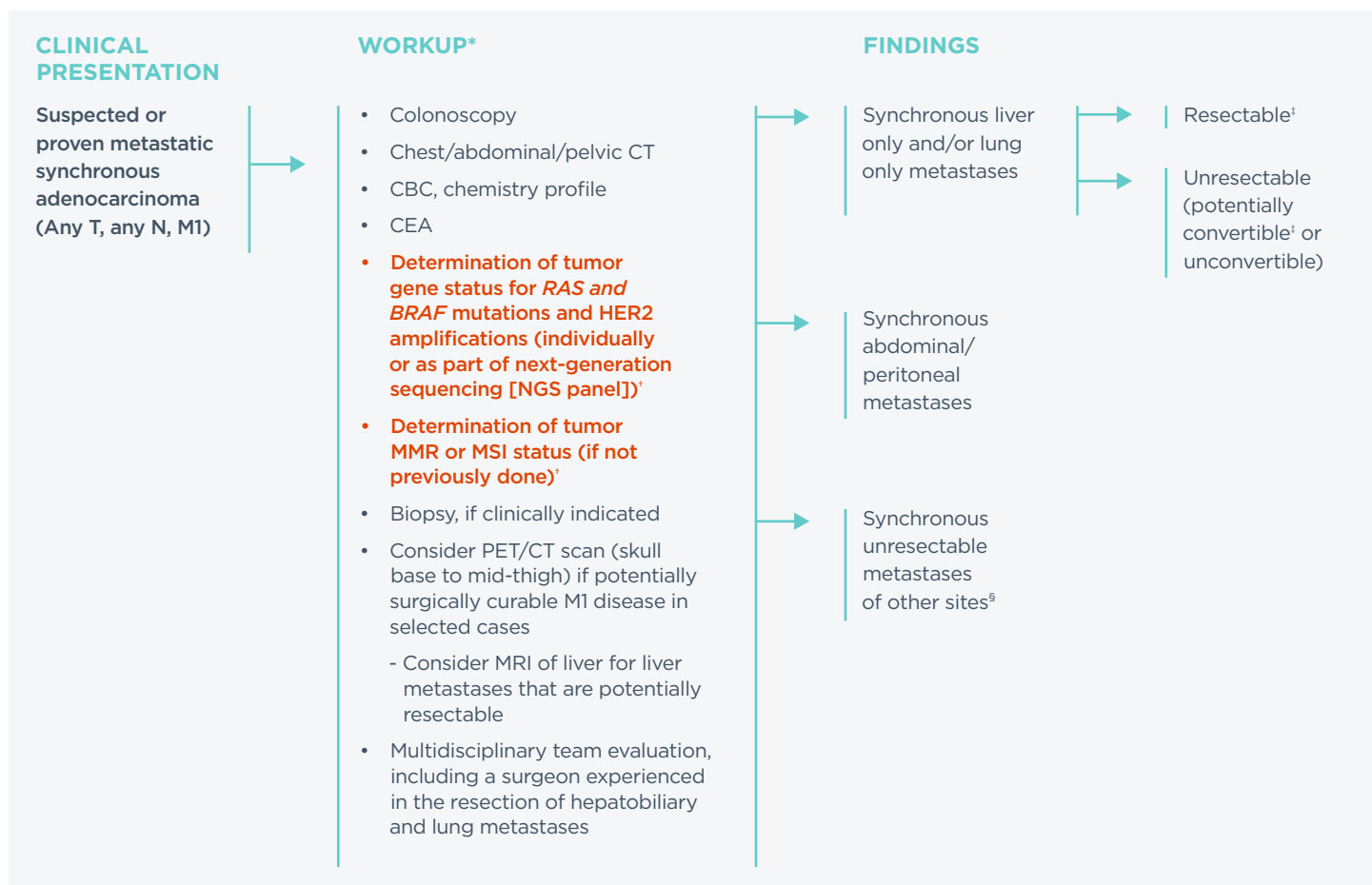
- Analyzes 70 genes
- Reports MSI-H status



* FoundationOne Liquid only reports MSI when determined to be high.

NCCN Clinical Practice Guidelines In Oncology (NCCN Guidelines®)

Version 1.2020 Colon Cancer



* See Principles of Imaging (COL-A).

† See Principles of Pathologic Review (COL-B 4 of 8) - *KRAS*, *NRAS*, and *BRAF* Mutation Testing and Microsatellite Instability (MSI) or Mismatch Repair (MMR) Testing. If known *RAS*/*RAF* mutation, *HER2* testing is not indicated. NGS panels have the ability to pick up rare and actionable mutations and fusions.

‡ See Principles of Surgery (COL-C 2 of 3).

§ Consider colon resection only if imminent risk of obstruction, significant bleeding, perforation, or other significant tumor-related symptoms.

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TO LEARN MORE:

Visit www.foundationmedicine.com

TO SIGN UP OR ORDER A TEST:

Visit www.foundationmedicine.com/signup

FoundationOne®CDx is the only FDA-approved *in vitro* diagnostic test by Foundation Medicine. FoundationOne Liquid and FoundationOne Heme were developed and their performance characteristics determined by Foundation Medicine. They have not been cleared or approved by the U.S. Food and Drug Administration. For more information on our laboratory developed tests please see Technical Specifications at <http://www.foundationmedicine.com>.

FoundationOne®CDx is a next-generation sequencing based *in vitro* test intended for use by healthcare professionals for advanced cancer patients with solid tumors. The test analyzes 324 genes as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB) and is FDA-approved as a companion diagnostic to identify patients who may benefit from treatment with a specific list of therapies (listed in Table 1 in the Technical Information at www.foundationmedicine.com/flcdx) in accordance with the approved therapeutic product labeling. Additional genomic findings, other than those listed in Table 1, 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 or clinical trial option, or that all relevant alterations will be detected. Some patients may require a biopsy. For the complete label, including important risk information, please visit www.foundationmedicine.com/flcdx.

References:

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- Medicare and Medicare Advantage members have coverage of FoundationOne CDx in accordance with the Centers for Medicare and Medicaid Services (CMS) national coverage determination (NCD) criteria.