January 17th, 2018

To: Centers for Medicare and Medicaid Services and Food and Drug Administration

To Whom It May Concern:

Fight Colorectal Cancer (Fight CRC), with input from members of our Medical Advisory Board, appreciates the opportunity to publicly comment on the proposed decision guideline for next generation sequencing (NGS) for Medicare beneficiaries with advanced cancer.

Fight Colorectal Cancer (Fight CRC) is the United States’ leading advocacy-focused colorectal cancer nonprofit. We envision victory over colon and rectal cancers. We serve as a resource for advocates, policymakers and medical professionals. Additionally, we lead efforts to increase and improve research of colorectal cancer at all stages and throughout the cancer continuum.

This proposed decision is a monumental step towards access to healthcare coverage for a large portion of the US population. Prior to the decision by the FDA and CMS, the process to receive NGS tests was fraught with difficulties such as access to testing, complex filing systems between patients and hospital systems, which often resulted in patients absorbing the costs. The quality and access of testing was variable and often not available to patients outside of academic medical settings. This decision allows for more routine, quality testing for Medicare beneficiaries, and as a leader in patient advocacy, we strongly support opportunities to increase access to healthcare.

As treatment decisions are often guided by diagnostic tests, the accuracy of the tests is as important as the efficacy of the treatment. To that end, we support the Proposed Decision Memo for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450N), with some comments and requests for clarification.

In the current Memo, patients with metastatic colorectal cancer will have coverage per the following guidelines:

A. Coverage

The Centers for Medicare & Medicaid Services (CMS) proposes that the evidence is sufficient to cover Next Generation Sequencing (NGS) as a diagnostic laboratory test, including the test results, when performed in a CLIA-certified laboratory and when ordered by a treating physician, and when both 1 and 2 are met.

1. Patient has:
a. recurrent, metastatic, or advanced stage IV cancer; and  
b. not been previously tested using the same NGS test; and  
c. decided to seek further cancer treatment (e.g., therapeutic chemotherapy)

2. The diagnostic laboratory test using NGS meets all the following criteria:  
a. the test is an FDA-approved companion in vitro diagnostic; and  
b. the test is used in a cancer with an FDA-approved companion diagnostic indication; and  
c. the test provides an FDA-approved report of test results to the treating physician that specifies FDA-indicated treatment options for their patient’s cancer.

We would appreciate a clarification on the following item and also wish to express our concerns:

“Patient has not been previously tested using the same NGS test”

This statement implies that a patient tested with one NGS test would not be able to be tested with the same test, but it’s not clear whether the patient would be able to be tested with a different test. This lack of clarity is concerning. In addition, there are growing data that suggests that primary tumors and metastatic disease have very different genetic profiles, and thus if a patient had initial testing, repeat testing of metastatic disease may be appropriate. Furthermore, for metastatic disease patients, overtime tumor genetic profiles change and it may be appropriate to repeat NGS testing for patients to guide future treatment decisions. Therefore, additional tests may be very appropriate, if not under Coverage then under Coverage with Evidence Development (CED).

Cancer patients, including CRC patients, often receive a combination of routine care or through a clinical trial. Consider this situation: a colorectal cancer patient received a covered NGS test shortly after diagnosis as part of routine care. Two years later, the patient is considering a clinical trial which requires a current NGS test as part of the entry criteria, and one of the CED NGS tests is an option. Would this patient be able to receive a second NGS test as part of the clinical trials?

We suggest that the issue of >1 test on the same patient be re-examined with these comments in mind.

A growing number of companion diagnostics being developed for specific drugs. This topic was discussed in a 2015 FDA-AACR-ASCO workshop (http://blog.aacr.org/fda-aacr-asco-workshop-complexities-in-personalized-medicine-harmonizing-companion-diagnostics/) where the number of PD/PD1 drugs and companion diagnostics was used as an example. Please consider
the situation where an anti-PD and companion diagnostic is approved for patients with metastatic colorectal cancer. Our assumption is that the covered NGS tests will include some version of the companion diagnostic; however, it may not be as specific as the companion diagnostic.

Specific Questions:
Will patients have access to both the covered NGS test and the companion diagnostic?
Will physicians assume that the test on the covered NGS test is the same as the companion diagnostic?
This issue is complex and probably beyond the scope of this Memo; however, we believe that it’s critical to consider the actual patient – physician interaction as the number of look-alike drugs / diagnostics increases.

In addition, we have heard concerns from many of our academic researchers regarding the impact this Coverage decision may have on academic pathology labs and patient impact. We acknowledge their concerns, as we believe that patients are best served when both academic and corporate research thrive. If this decision leads to the closing of pathology labs, especially at research centers, we are concerned this may create a limitation in quality and access to some patients.

Regarding the Memo and the discussion of CED, we strongly support the requirement that the tests be covered if data is gathered. This data will help assess the actual clinical validity of the NGS tests. We appreciate the partnership of CMS with the NCI NCTN network trials, because CED of these tests will help these critical trials accrue more patients over the age of 65.

In the process of reviewing this issue with our Medical Advisory Board, collection of registry data was noted as a potential laborious step for physicians; particularly physicians who don’t routinely participate in research. We suggest the entities supporting this initiative might work with practitioners to examine novel ways to populate the registries – for example, by automating extraction of information from the electronic health records. Similarly, there are concerns about the patient-reported outcomes data requirement. Unfortunately, there is a growing demand on clinicians in terms of utilizing electronic medical records, which can become costly and timely. While collecting data is a necessary step, it is crucial to find an efficient way to do so. The administrative and data gathering time, is reducing the amount of time clinicians truly can dedicate to the art of medicine and one-on-one time with patients.

A specific consideration, is as it’s common for newly-approved drugs to enter registry trials, as a way to evaluate their impact in a more real-world setting (Genentech has a history of such
registries). Perhaps there are lessons learned in the drug world which could be applied to the device world and this is a discrete example.

Based on our experience with the patient community and leading experts guiding care, the above comments encapsulate the most pressing concerns which reflect the perspective of colorectal cancer patients. By in large, we feel this coverage announcement provides further opportunities to improve these types of tests, ultimately keeping the patient’s best interest in mind.

We support the proposed decision memo and understand it is an important next step for expanding coverage for Medicare beneficiaries with Advanced Cancer. Ultimately, we hope that our comments on the proposed guideline will lead to better diagnostics and treatment options for patients.

Thank you for allowing an opportunity to comment and taking into consideration our comments and concerns.

Sincerely,

Anjee Davis, MPPA
President
Fight Colorectal Cancer

*Fight Colorectal Cancer believes in fully disclosing all potential conflicts of interest. As an organization, we have received sponsorships and/or educational grants from companies who have an interest in novel screening methods for colorectal cancer, including: Foundation One, Caris, Genomic Health, and Quest. It is important to note however that none of these companies or additional sponsors have influenced the following comments.*