ALK POSITIVE

Worldwide Information, Support, and Empathy

https://www.alkpositive.org

January 17, 2018

To the Centers for Medicare & Medicaid Services:

Re: Proposed Decision Memorandum on Next Generation Sequencing ("NGS") for Medicare Beneficiaries with Advanced Cancer

We represent the community ALK Positive, a group of more than 800 survivors and caregivers of individuals with advanced anaplastic lymphoma kinase ("ALK") positive Non-Small Cell Lung Cancer ("NSCLC"). ALK translocations in NSCLC are estimated to affect approximately 5% of NSCLC patients, and almost all of ALK positive cancer diagnoses are found at advanced stages, most frequently stage IV. The importance of testing for ALK, for all oncogenic mutational drivers of lung cancers is critical: finding the ALK translocation will directly impact a patient's treatment course and his or her survival. Only a fraction of NSCLC patients are provided genomic testing at diagnosis, and we applaud the Proposed Decision Memorandum's ("the Proposal") coverage of NGS for Medicare beneficiaries. We believe this testing will result in more people learning that their cancer is driven by a mutation/translocation, which will inevitably result in more effective, sustained treatments.

ALK positive patients currently have access to four Food and Drug Administration ("FDA") approved tyrosine kinase inhibitors ("TKIs") (Crizotinib, Ceritinib, Alectinib, and Brigatinib, with two other medications in Phase III clinical trials Ensartinib and Lorlatinib). While there are differences, these TKIs effectively keep the cancer at bay for a time, ranging from several months to sometimes years in some patients, with far fewer side effects than traditional treatments.

Due to drug resistance, the TKI inhibitor will inevitably fail, and, patients then move onto another TKI. Approximately 50% of ALK positive patients' cancers will develop a sub-mutation, and those mutations often vary from patient to patient. Research has shown that certain second and third generation TKIs can treat certain sub-mutations very effectively. Other TKIs

may be known to be completely ineffective against a particular ALK sub-mutation. The only way to find out which sub-mutation has developed, however, is a subsequent NGS test. Yet the Proposal only pays for one NGS test.

CMS is asking Medicare patients and their doctors to play darts blindfolded by failing to fund testing for these sub-mutations on a second, or a third NGS test, after each TKI medication has failed. This is unnecessary, dangerous to the patients, and financially wasteful. Precision medicine requires precision testing.

This guessing game is unnecessary because assays, either through FoundationOne, academic institutions, or others, currently exist that can identify sub-mutations, which can accurately guide a doctor's prescribed next course of treatment. It is dangerous because subjecting a patient to a treatment that likely won't work will inevitably worsen his or her condition, if not hasten their death. Please make no mistake: the failure to do subsequent NGS tests can and will lead to the premature deaths of patients. Finally, the suggestion to test only once is financially wasteful; it will cause doctors to prescribe medication costing approximately $15,000 a month and might not work when a test could determine a medication's effectiveness for a fraction of the price. In other words, by failing to allow for subsequent NGS testing, the Proposal is "penny wise but pound foolish."

We are also concerned about the Proposal's lack of testing options for which CMS proposes to pay. While FoundationOne has been very beneficial to our members, so have many other NGS tests by both commercial and academic providers. Problematically, many of the members of our group have provided tissue samples to more than one provider, and obtained differing results. A doctor and a patient should make the decision as to where to send biopsy samples, factoring in the type of sample, suspected type of mutation, etc., without having to worry if CMS is going to pay for it.

We are also troubled by the conditional manner in which CMS proposes to pay for a test. If a patient tests negative for a useful biomarker, or tests positive for a biomarker that does not yet have an FDA approved companion diagnostic, all patients who wish CMS to cover their NGS test must be prepared to enter a patient registry, enroll in a clinical trial, or pay for the test themselves.

Any of these conditions place unacceptable burdens on patients. A patient should not have to waive his or her privacy rights in order to get a genomic test. Yet this is exactly what the Proposal demands. Privacy is important to patients. Cancer patients are subjected to a seemingly endless barrage of invasive procedures as part of their treatment. Many patients feel the only thing they can control is their own privacy. Patients should not be forced to give that up due to a patient registry enrollment requirement, in order to get access to potentially life-saving genomic testing. Further, it is not at all clear to what end the patient registry or

registries will be used. While ALK Positives can and do support the rational collection of data so as to spur medical advancements, there are inadequate safeguards in place here to preserve patient privacy, and in no event should a registry be compulsory.

While the goal of increasing clinical trial participation is commendable, forcing patients to enter a clinical trial in order to have access to NGS testing is not appropriate. Clinical trial sites for patients are often few and far between. It is not uncommon for our members to travel many hundreds, if not thousands of miles, for clinical trial appointments. There is a substantial time commitment to most clinical trials and the transportation costs are rarely, if ever, reimbursed. Frankly, most Americans cannot afford the time and expense to participate in a clinical trial. There are many advantages to clinical trials, but there are many potentially serious drawbacks as well. Simply put, CMS should not require patients to subject themselves to experimental treatments in order to have access to a potentially life-saving test. The Proposal erodes the historic and, crucially, voluntary nature of clinical trial enrollment. Encouraging participation in clinical trials is critically important, but this is not the mechanism by which to do it.

ALK Positive members applaud the proposed coverage of NGS testing. However, we find three significant flaws in the Proposal that must be corrected and we respectfully request the following changes to the Proposal:

1) to pay for multiple NGS tests, as required by the patient's doctor, instead of the current proposal to pay for the same test once;
2) to have CMS cover the costs of several types of NGS tests, instead of the current proposal that unnecessarily limits the types of tests that CMS will cover; and
3) to pay for the NGS tests without requiring a patient to waive their privacy rights and/or force their participation in clinical trials, instead of the current proposal that inappropriately conditions payment for the NGS test on a patient's waiver of privacy rights and/or forced enrollment in a clinical trial.

Thank you for your consideration.

ALK Positive