January 17, 2018

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Ms. Verma:

The five undersigned organizations request that you do not finalize the National Coverage Analysis entitled, Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer, as currently drafted. Our organizations are deeply concerned about the broad scope of the proposed decision memo and ask that the Centers for Medicare & Medicaid Services (CMS) further engage with stakeholders to better understand how this policy, if finalized, will impact the access of Medicare beneficiaries to tests utilizing NGS technology for cancer and other conditions.

Our groups represent patients and cancer care professionals and we support the goal of the Food and Drug Administration (FDA) and CMS' Parallel Review program to streamline the approval and coverage processes. We also applaud the agency for recognizing the value of precision oncology diagnostics in the care of cancer patients by proposing coverage for FoundationOne CDx (F1CDx). To be clear, we do support a positive coverage determination for the product reviewed in the Parallel Review program, F1CDx, and hope CMS will move swiftly to implement its coverage.

However, the additional policy outlined in the proposed decision memo goes way beyond the focus of that product. It sets policy for the entire country with coverage so narrowly defined, that we are concerned that it would severely restrict patients' access to other potentially lifesaving testing using NGS-based technology. Not only does the policy limit coverage to FDA approved NGS-based tests with companion diagnostic indications used in cancer, but it imposes very narrow criteria for coverage with evidence development for other FDA cleared or approved NGS based tests and makes explicit a policy of non-coverage for all NGS-based tests that do not meet the listed criteria. Furthermore, this would supersede existing local coverage policies finalized by Medicare Administrative Contractors (MACs) for most NGS-based tests that are currently being performed at academic medical centers, leading cancer institutions, and community cancer centers, further limiting Medicare beneficiaries' access to necessary diagnostics.

The patients we represent and treat are benefitting from advances in the understanding of the genomic causes of cancer, both in increased access to targeted therapeutics and in innovative diagnostics that improve their ability to prevent cancer and monitor disease progression. Again, we support CMS' proposal to cover (F1CDx) as it provides meaningful and actionable information for Medicare beneficiaries with advanced cancer. However, we believe CMS should not finalize the rest of the policy contained in the proposed decision memo and instead, convene a meeting with interested stakeholders to ensure that Medicare coverage policy enables patient access to valid and clinically relevant NGS-based tests without eliminating the importance of local expertise in this area or stifling innovation.

Thank you for your thoughtful consideration of this request. We look forward to working with you to improve this policy and protect Medicare beneficiary access to NGS-based testing that is valid and clinically relevant.

Sincerely,

Association of Community Cancer Centers
International Myeloma Foundation
Myeloma Crowd
National Organization for Rare Disorders
Susan G. Komen

cc: Honorable Mitch McConnell
Honorable Chuck Schumer
Honorable Paul Ryan
Honorable Nancy Pelosi
Honorable Orrin Hatch
Honorable Ron Wyden
Honorable Lamar Alexander
Honorable Patty Murray
Honorable Kevin Brady
Honorable Richard Neal
Honorable Greg Walden
Honorable Frank Pallone