Society for Women's Health Research

January 31, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue SW
Washington, DC 20201

Re: CMS Implementation of National Coverage Determination for Next Generation Sequencing for Medicare Beneficiaries with Advanced Cancer

Dear Administrator Verma:

I am writing on behalf of the Society for Women's Health Research (SWHR) to express our serious concerns with the December 2018 published guidance from the Centers for Medicare & Medicaid Services (CMS) to the Medicare Administrative Contractors (MACs) on National Coverage Determination (NCD90.2) for Next Generation Sequencing (NGS).

SWHR is a nearly 30-year-old education and advocacy nonprofit dedicated to promoting research on biological differences in disease and improving women's health through science, policy, and education. From our work studying a range of acute and chronic diseases that exclusively, disproportionately, or differently affect women, we know that restricting patient access to medically appropriate, health care provider-recommended diagnostic tests can have devastating consequences on patient health outcomes, functional status, pain, and even survival.

SWHR is very concerned that the agency's broad interpretation of the NCD will negatively affect women and inhibit investment in women's health innovations. This rendering also is counter to the primary goals of personalized medicine and public health. It is our understanding that for several years MACs have provided coverage for medically appropriate NGS-based tests, including those for germline breast and ovarian cancer syndromes and Lynch syndrome in patients who do not have advanced cancer.

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Testing for germline variants that are inherited by every cell in the body can reveal whether an individual is at risk for a hereditary disease. In recent years, NGS technologies have played an essential role in advancing the understanding of altered genetic pathways involved in human cancer, including certain cancers for which women are genetically predisposed. For example, women with BRCA1 or BRCA2 mutations are at increased risk for breast and ovarian cancer. Early targeted detection allows treatment to start sooner and may even prolong survival if a woman's disease is caught before it reaches an advanced stage. Diagnostic tools that may profoundly improve patient health outcomes and survival rates are rare successes in medicine that must be made accessible to patients when clinically appropriate.

Yet, we know that at least one Medicare contractor, Palmetto, recently has revised its local coverage determination (LCD) for BRCA1 and BRCA2 testing to align it with the NCD. In doing so, Palmetto has indicated that it will not cover NGS-based tests to determine whether women with stage 1 or stage 2 cancer have an inherited predisposition for breast and ovarian cancer. Taking such an overly broad interpretation of the NCD will deny women critical access to cutting-edge, FDA-approved molecular tests on NGS platforms, and is a step in the wrong direction for Medicare, beneficiaries, and personalized medicine. **As such, I urge CMS to a) revise its interpretation of the NCD immediately to explicitly clarify that the NCD applies to somatic tumor testing only and b) communicate this policy interpretation expeditiously to MACs.**

Thank you for your consideration of our comments and CMS' prompt attention to this important matter. If you have questions, please contact Sarah Wells Kocsis, Vice President, Public Policy, at 202.496.5003 or swellskocsis@swhr.org.

Sincerely,

Amy M. Miller, PhD
President and Chief Executive Officer
Society for Women's Health Research

cc: Tamara Syrek Jensen, JD, Director, Coverage & Analysis Group, CMS