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**BIO Comments Re: Proposed National Coverage Determination for Diagnostic Laboratory Tests using Next Generation Sequencing (NGS) for Medicare Beneficiaries with Germline (Inherited) Cancer (CAG-00450R)**

Dear Madam/Sir:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS') National Coverage Determination for Diagnostic Laboratory Tests using Next Generation Sequencing (NGS) for Medicare Beneficiaries with Germline (Inherited) Cancer.

BIO is the world's largest trade association representing approximately 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. Specifically, many of BIO's members develop, market, or are impacted by diagnostic technologies for a variety of research, investigational, and clinical uses. BIO's members also develop therapeutic products that are guided by diagnostics tests that provide the right treatment for the right patient at the right time—the essence of the modern precision medicine paradigm.

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Diagnostic technologies, such as next generation sequencing (NGS) testing for cancer diagnosis and treatment, play a pivotal role in personalized medicine, allowing an individual's genetic profile to guide decisions regarding prevention and treatment of serious health conditions. The availability of high-quality molecular profiling advances access to the most appropriate course of therapy in a more expeditious and efficient manner. Providing coverage for technologies and tools that advance patient access to the most appropriate course of treatment helps to improve health outcomes and reduce overall healthcare spending in the short- and long-term. We are appreciative of the revisions proposed by the Agency in this Proposed Decision Memorandum, which signify CMS' recognition that germline mutations may inform treatment options and cancer risk for patients.

BIO supports CMS coverage and reimbursement for validated NGS testing as it reduces barriers to access, helps to ensure safe and effective use of medicines for patients with serious diseases to ensure they receive the highest standard of care and more personalized treatment. It is critical that as the science of cancer treatment continues to evolve, Medicare beneficiaries are able to access the full range of testing and treatments available for their given condition. High quality, validated genomic profiling assays accelerate patient access to precision approaches to diagnosing and treating cancer.

BIO appreciates that CMS has made efforts to address stakeholder concerns with the NCD's prior language regarding clinical needs for multiple NGS tests for the same diagnosis. However, we are concerned that the revised language may inappropriately limit access to a germline NGS test for a patient who has previously received a somatic NGS test—or alternative germline NGS test—that is wholly unrelated to the advanced cancer for which this current germline NGS test is approved. The NCD currently places a lifetime limit on coverage for the use of the same NGS-based test on a patient, and we believe this limit should be removed based on the growing body of evidence that has established the value of multiple NGS tests throughout the duration of a patient's treatment. BIO's understanding is that it is common in clinical practice for a physician to order multiple NGS tests—including retests, confirmatory tests or repeat testing—for the same diagnosis. However, we interpret the current language to omit important coverage of multiple tests, including retests, confirmatory tests and repeat testing. BIO would urge CMS to reconsider the coverage limitations for a patient whose physician has determined additional testing is needed—when reasonable and necessary—or for whom previous NGS testing was completed for a condition related to or unrelated to the existing cancer.

BIO understands the proposed coverage requirement for NGS testing to be "FDA approved or cleared for indication for use in that patient's cancer." However, BIO is concerned that this limitation may lead to coverage gaps for ovarian and breast cancer patients with specific mutations that are only identified by tests that are not yet approved or cleared by the FDA. While BIO maintains longstanding support for

the rigorous standards of safety and efficacy ensured by regulatory approval of NGS testing, we also appreciate that existing tests have not yet reached this benchmark. This may be problematic because CMS proposes to provide discretion to the Medicare Administrative Contractors (MACs) for coverage of NGS testing germline mutations for patients with a cancer diagnosis *other than* breast or ovarian. Perhaps most importantly, it is problematic that there are currently no FDA approved or cleared germline NGS tests for breast or ovarian cancer. Patients would benefit from MACs that are permitted more flexibility to analyze and cover innovative tests. Given the prospective negative impact to patients if these tests (which MACs cover today) effectively become non-covered nationally, we would encourage CMS to allow MACs to continue to provide important coverage for non-FDA approved or cleared NGS testing for patients with breast and ovarian cancer.

BIO believes this NCD is an important milestone in addressing unmet patient need in breast and ovarian cancer. Identification of mutations to deliver more targeted treatment and care can help ensure beneficiaries receive more timely access to the most appropriate treatment, improve overall health outcomes, and reduce spending on other treatments. We encourage CMS to engage with stakeholders to work through the issues identified above as well as furthering access to NGS tests in other therapeutic areas.

BIO appreciates this opportunity to comment on CMS' National Coverage Determination. We would be pleased to provide further input or clarification of our comments, as needed, and should you have any questions about the content of this letter, please contact Jeremy Isenberg, Manager for Health Policy, at jisenberg@bio.org.

Sincerely,

/S/

Jeremy Isenberg

Manager, Health Policy
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