December 2, 2019

Tamara Syrek Jensen, JD
Director, Coverage & Analysis Group
Center for Clinical Standards and Quality
Centers for Medicare & Medicaid Services
Mailstop S3-02-01
7500 Security Blvd
Baltimore MD 21244

RE: National Coverage Analysis (NCA) for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450R)

Dear Ms. Syrek Jensen:

The Advanced Medical Technology Association (AdvaMed) and AdvaMedDx commend the Centers for Medicare & Medicaid Services’ (CMS) for reopening the National Coverage Determination (NCD) for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer.1 We are pleased to offer the following comments on the proposed Decision Memorandum.

AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMedDx functions as an association within AdvaMed and its member companies produce advanced in vitro diagnostic tests that facilitate evidence-based medicine, improve quality of patient care, enable early detection of disease and often reduce overall health care costs. Our membership includes manufacturers engaged in the development of innovative diagnostics that support the advancement of public health, including next generation sequencing-based technologies. Throughout this letter, AdvaMed refers to both AdvaMed and AdvaMedDx.

We appreciate the opportunity to provide comments on the proposed expansion of coverage of NGS-based testing to germline (inherited) testing. These important tests and technologies play an integral role in personalized medicine and patient care management, and therefore access to these tests is critical for Medicare patients. We also appreciate and support the proposal to allow Medicare Administrative Contractors (MAC) the necessary discretion to consider and determine coverage of NGS-based germline testing for other cancers, where the status of the evidence is rapidly evolving.

As we have previously noted, NGS is a tool that can be used for many applications, from hematology/oncology to immunology and more. We continue to support creating a rational path to coverage for additional uses of NGS (such as initial diagnostic assessment, tracking diseases longitudinally, or where companion designation of a test is not plausible). Patient access to new NGS-based tests must be able to keep pace with the development of new clinical utility evidence.

**Application to Testing for Germline Mutations and Hereditary Cancers**

We appreciate CMS’s proposal to expand coverage under the draft NCD to germline mutation testing. We support CMS’s conclusions that the available evidence supports use of NGS as a diagnostic test for patients with risk factors for germline ovarian or breast cancers, where clinical indications for germline testing exist and the results of the test could impact the clinical management of those patients.

We note that the literature and existing guidelines do not distinguish between testing performed on an NGS platform and testing using other sequencing methods, such as Sanger sequencing, and we continue to voice our concerns that this will lead to disparate coverage policies for the same type of testing when performed on different platforms. Numerous existing tests performed on platforms other than NGS are migrating to NGS platforms. It would be non-sensical for Medicare coverage policy to cover a diagnostic test as reasonable and necessary when performed on one platform, but to non-cover an NGS-version of the same test.

**Application to Testing for Treatment Monitoring and Repeat Testing**

Many NGS-based diagnostic tests are indicated to aid in identifying patients who are eligible for targeted therapies regardless of the stage of cancer and/or recurrence. The proposed NCD, even with its proposed coverage expansion, still prohibits coverage of NGS-based testing for patients with earlier stage cancer and testing that requires repeated use of the test over time, such as identifying minimal residual disease or other monitoring uses. The NCD should not be a barrier to future developments in the field.

**Local Coverage Determinations for NGS as a Diagnostic Test**

AdvaMed supports CMS’ proposal to allow discretion for MACs to determine coverage of NGS-based diagnostic tests for patients with cancer diagnoses other than breast or ovarian cancers (e.g., prostate cancer). We agree that CMS coverage policy should not foreclose coverage in other cancers where the state of the evidence is continually evolving.

We urge CMS to remain flexible in its approach to coverage of future uses of NGS as a diagnostic test. Inevitably, new discoveries will continue to unfold, and important new therapies will be developed, outside of breast and ovarian cancer, including non-cancer uses. A

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flexible approach will safeguard existing coverage policies that predated the NCD, and enable coverage, either through national coverage or MAC discretion, that can provide clinicians and their patients access to this valuable tool as evidence is generated for new clinical uses.

**Title Change and Other Technical Revisions**

Finally, AdvaMed recommends that CMS revise the title of the NCD and make other technical revisions for conformity.

- We recommend revising the title of the NCD to reflect the expansion of coverage beyond patients with advanced cancer. AdvaMed supports other stakeholders’ recommendations to revise the title to “Next Generation Sequencing (NGS) for Treatment and Management of Cancer.” This title change would reflect CMS’s recognition of new, additional benefits of NGS as a diagnostic test, and would also keep open the potential for additional expansions of coverage in the future.

- We recommend specific changes in the new NCD language for germline testing. In two places, CMS uses the phrase “not been previously tested using NGS.” We believe this statement was not intended as drafted and should be revised to read “not been tested previously for the same germline gene or genes using NGS.”

The language in the existing NCD (for patients with advanced cancer) reads “not been previously tested using the same NGS tests for the same primary diagnosis of cancer, or repeat testing using the same NGS test only when a new primary cancer diagnosis is made by the treating physician.” The language in the new section for germline testing should follow a similar rationale. A patient could, for example, have had prior NGS testing for another condition (e.g., a cardiac condition, sepsis, or other reason); however, this should not preclude the patient from receiving an NGS-based germline test.

- We recommend that CMS revise the language that follows section B.2. (under “Nationally Covered Indications”):

  Effective for services performed or after [Month/XX][Day/XX], [20XX], the CMS proposes that NGS as a diagnostic laboratory test is reasonable and necessary, and covered nationally, when performed in a CLIA-certified laboratory, when ordered by a treating physician and when all of the following requirements are met:

- We recommend that CMS revise the reference to Section B.1 in Section C (Nationally Non-Covered) to Section B as follows:

  Effective for services performed or after March 16, 2018, NGS as a diagnostic laboratory test for patients with cancer are non-covered if the cancer patient does not meet the criteria noted in Section B.1 above.
• We recommend that CMS add language at the end of Section D. (Other):
  Other uses of NGS testing in patients with cancer, not precluded by Section C, remain
at the discretion of the Medicare Administrative Contractors (MACs).

Thank you for the opportunity to provide these comments. Please feel free to
contact me at cbranham@advamed.org if you have any questions concerning these comments.

Sincerely,

Chandra N. Branham, JD
Vice President, Payment & Health Care Delivery Policy
AdvaMed