



ASSOCIATION FOR MOLECULAR PATHOLOGY
Education. Innovation & Improved Patient Care. Advocacy.
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January 25, 2018

The Honorable Alex Azar
Secretary
Department of Health and Human Services
Humbert Humphrey building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Request for Information on Promoting Healthcare Choice and Competition Across the United States

Dear Secretary Azar:

The Association for Molecular Pathology (AMP) is pleased to offer comments on the Request for Information entitled, Promoting Healthcare Choice and Competition Across the United States. We appreciate that the agency is requesting information about barriers to choice and competition and proposed solutions that could facilitate the development and operation of a healthcare system that provides high-quality care at affordable prices for the American people.

We would like to focus on two topics regulated by the Centers for Medicare and Medicaid Services (CMS) that hamper patient access to affordable and clinically actionable health care services:

- **The National Coverage Analysis on Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG #00450N)¹**
- **Broad adoption and expansion of the MoIDx Program originally developed by Palmetto GBA²**

AMP is an international medical and professional association representing approximately 2,300 physicians, doctoral scientists, and medical technologists who perform, or are involved with, laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Membership includes professionals from academic medicine, hospital-based and private clinical laboratories, the government, and the in vitro diagnostics industry.

Molecular pathology professionals and the testing procedures that they develop, validate, and perform are essential to the clinical care team, especially at the fore of advancing medicine and innovative practice. As a clinical medical society, AMP is committed to advancing the field and practice of molecular pathology, protecting patients, and improving the adoption of innovative technologies and testing procedures into clinical practice. To help achieve this, AMP actively engages with policymakers as a trusted expert. AMP is committed to working with HHS and its retrospective agencies including CMS, and Medicare Administrative Contractors (MACs), and additional relevant stakeholders to ensure proper coverage and reimbursement policies are in place to ensure patient access to high-quality, appropriately priced molecular diagnostics.

¹ <https://www.cms.gov/medicare-coverage-database/details/nca-proposed-decision-memo.aspx?NCAId=290&bc=AAAAAAAAAAQAAA%3D%3D>

² <https://www.palmettogba.com/moldx>

AMP is concerned that both the proposed National Coverage Analysis on NGS for Medicare Beneficiaries with Advanced Cancer and the expansion of the MoDx Program administered by Palmetto GBA both present barriers to choice and competition within the American healthcare system.

Proposed Decision Memorandum on NGS for Medicare Beneficiaries with Advanced Cancer

The Centers for Medicare and Medicaid Services (CMS) recently closed the comment period on this national coverage analysis (NCA). Response to the comments submitted as well as a decision about the proposed NCD are anticipated in the near future. If finalized as proposed, the policy will limit access to NGS-based testing for Medicare patients with cancer. In our comments on the NCA, which can be found in their entirety [here](#), we made the following recommendation:

AMP recommends CMS refocus this policy so that it applies ONLY to FDA-approved NGS-based tests (such as the FoundationOne CDx (F1CDx) assay) and does not apply to any other NGS-based test. Coverage for other clinically- and analytically validated NGS-based tests should continue to be covered as determined by existing local coverage determinations (LCDs) administered by MACs. This approach will be much less disruptive, allowing ongoing coverage evaluation and clinical scientific progress to continue and for coverage policies to respond more quickly to changes in the science.

If finalized as written the NCA would eliminate existing coverage for testing procedures that are not FDA approved and concentrate testing to only a few commercial entities. There is no precedent or justification for producing an overly broad, universal, and method-specific NCD in response to a voluntary proposal by a single company for a single test. By broadening the scope, CMS imposes restrictive criteria on other tests using a similar, but not identical, methodology. These tests are currently recognized as the standard of care and are being used to deliver high-quality, advanced cancer care across the country. While some NGS based testing is restricted to clinical trials, there is extensive utilization of NGS-based testing in the clinical realm as evidenced by laboratories across the spectrum, including community medical centers, academic medical centers, and separate molecular pathology laboratories offering services.

Precision oncology is a medical practice that occurs at the local level, at the patient's bedside, and in interactions between local healthcare professionals including molecular pathologists. The flexibility to triage urgent patient samples, to discuss in depth the findings at local tumor boards with a multidisciplinary team, provide medical education and training, and to participate in quality improvement initiatives specific to institutions will all be lost if testing is effectively centralized to one national laboratory as proposed by this NCA. To date, coverage of this testing has been determined individually by the MACs. We support continuance of that approach as it provides opportunity for coverage policy to be developed better suited to local needs and changes in the standard of care.

AMP believes the broadly restrictive nature of the preliminary NCA could potentially stifle innovation, a hallmark and highlight of the American healthcare system. Particularly in these areas where the science is advancing rapidly, coverage policy must remain nimble to adapt to advances in understanding in the science and application to good patient care.

The difficulty and infrequency of modifications to national coverage determinations raises additional concerns. We are confident the rapidly-changing state of the science in this area will require frequent, multiple revisions of this policy if finalized as proposed. For these reasons, coverage of NGS-based testing is better suited at the local level through the ongoing LCD process.

Broad Adoption and Expansion of the MoIDx Program

AMP is extremely concerned about the broad adoption and further expansion of the MoIDx Program by Palmetto GBA and believes it violates CMS' competitive goals for retaining a local coverage process, imposing unnecessary expense and administrative burden for Medicare providers in MoIDx jurisdictions. Six MAC jurisdictions, including 26 states, American Samoa, Guam, and the North Mariana Islands, now operate under this program, representing half of the MAC jurisdictions.

Although the *Protecting Access to Medicare Act* (PAMA) granted CMS the authority to consolidate the number of MACs for policy and claims processing, in rulemaking the agency made the decision not to do so at the time. AMP believes that the continued expansion of the MoIDx program stifles innovation and competition in this market, as well as conflicting with CMS policy on MAC consolidation. The MACs who have adopted MoIDx are adopting Palmetto's coverage policies almost verbatim. In essence, every MAC that signs on to MoIDx cedes its responsibility and authority for coverage determination to Palmetto's MoIDx program. Consequently, the coverage determination process in each MAC jurisdiction becomes a pointless exercise under which these MACs go through the required motions rather than issuing policies with a genuine interest in responsibly determining local coverage policy.

AMP continues to believe that patients, providers, and the greater medical community are best served by a coverage determination system for clinical laboratory services that relies on the presence of multiple MACs. There is great diversity in the way MACs use standards for information gathering and review, as well as the nature and visibility of the relationship the MAC's have with stakeholders. A multiple-MAC system allows patients and providers to advocate directly to their MAC and increases the potential for invaluable scientific discourse and dialogue between stakeholders and payers.

AMP agrees with CMS' decision not to reduce the number of MACs, but believes that there is a *de facto* decrease in the number of MACs responsible for policy on molecular diagnostics, resulting in a loss of the diversity of approaches to coverage policy supported by the current scheme. Competition and diversity of input is critical to any process with multiple stakeholders who carry high risk, including the development of coverage policy. Competition and diversity ensure a full complement of evidence and experience is considered in coverage determinations. Losing diversity in the process would be particularly harmful in the field of molecular diagnostics where technology is rapidly advancing and bringing new opportunities for substantial patient benefit. Practitioners and stakeholders at AMP and other specialty groups keep abreast of the advances in molecular diagnostics as they occur. Close communication and collaboration between the MACs and professional societies who harbor the brain trust of advancing science, including AMP, is the best way to ensure that coverage determinations are made using the best and most current science.

Thank you again for this opportunity to respond to this Request for Information. We believe these two issues present real opportunities to ensure that administration policies do not infringe on patient access to medically reasonable and necessary care and preserve competition in the healthcare market. AMP welcomes the opportunity to work with you and those at CMS responsible for oversight of these issues. Please direct any follow up correspondence to Tara Burke, AMP Director of Public Policy and Advocacy, at tburke@amp.org.

Sincerely,

Samuel K. Caughron, MD
Chair, Economic Affairs Committee
Association for Molecular Pathology