



ASSOCIATION FOR MOLECULAR PATHOLOGY

Providing global expertise in molecular testing that drives patient care

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December 16, 2019

The Honorable Diana DeGette
U.S. House of Representatives
Washington, DC 20515

The Honorable Fred Upton
U.S. House of Representatives
Washington, DC 20515

Dear Representatives DeGette and Upton:

On behalf of the Association for Molecular Pathology (AMP), we appreciate the opportunity to submit this response to the “Call to Action” for Cures 2.0. AMP is an international medical and professional association representing approximately 2,500 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 the government, academic medicine, private and hospital-based clinical laboratories, and the in vitro diagnostics industry.

We commend Reps. Upton and DeGette for recognizing that barriers exist within Medicare coding, coverage, and existing payment constructs and for proposing within Cures 2.0 to support access to life-saving cures by exploring reform in these areas. To better support patients’ access to innovative therapies, AMP encourages Reps Upton and DeGette to use Cures 2.0 to address reimbursement hurdles facing molecular diagnostic testing. Molecular diagnostic testing is the keystone of precision medicine, where physicians and patients use the results of these tests to help guide therapy and disease management. A stable and equitable reimbursement environment for these tests is needed to ensure patient access to innovative therapies.

We have identified several key areas within the policy landscape for molecular diagnostic testing that currently work against patient access to life-saving cures and where our members face unnecessary burdens to deliver innovative care to patients. Below, we provide a brief summary of each problem and proposed recommendations for solutions. As you work to consider specific issues you wish to address in this legislation, we kindly request you consider the recommendations below.

Coding, Coverage and Payment Barriers to Innovative Care

As we begin to realize the promise of precision medicine, barriers in coding, coverage and reimbursement are working against this progress by preventing patient access to these lifesaving therapies and diagnostics. There are several policies which place an undue burden on the practice of medicine, leading to delays in access to care for patients.

Coverage

Section 90.2 of the Medicare National Coverage Determinations (NCD) Manual states conditions of coverage for next generation sequencing (NGS). Specifically, CMS established coverage of NGS as a diagnostic laboratory test when performed in a Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory and ordered by a

treating physician, as long as specific criteria are met. AMP remains concerned with CMS's NCD for NGS for Medicare Beneficiaries with Advanced Cancer (CAG-00450R), which is a coverage policy based on broad applications of a specific methodology or technology platform, NGS in this case, rather than a specific diagnostic test. This distinction has led to a number of unanticipated consequences and has resulted in effective non-coverage for many clinically-necessary, and commonly-used, NGS-based tests. Instead, CMS should review evidence and practice guidelines for clinical indications of testing that are related to the biomarkers being tested, not for the sequencing methodology.

Evidence-based guidelines from the National Comprehensive Cancer Network, American Society of Clinical Oncology, American Society of Hematology, AMP, College of American Pathologists, and World Health Organization support the clinical utility of molecular alterations in various diseases but do not specify the technologies utilized to detect those methods. These guidelines recognize that such alterations can also be detected by other non-NGS technologies, and as such, CMS coverage policies should not be restricted to a specific method, but should be designed to address the genetic alteration(s), cancer type, and targeted therapy combination that together defines clinical relevance.

CMS is currently in the process of reconsidering this NCD and a final policy is expected January 27, 2020¹. Each time AMP has commented on this policy, we have repeatedly recommended that CMS redesign the NCD to be based on the biomarker tested and to be agnostic to the methodology used, since the same biomarker can be analyzed using different types of testing methodologies^{2,3}. By initially focusing on evaluating the NGS-based technology as a whole, CMS will regularly need to revise the NCD, which will stifle innovation in the field and limit patient access.

As personalized treatments continue to evolve, CMS will need to be prepared to develop coverage policies that accurately reflect the advanced technology and utility of clinically-useful, commonly-used tests. Without access to molecular diagnostic testing, there is no personalized medicine. **To ensure national coverage policies are developed appropriately for rapidly evolving areas, such as molecular diagnostic testing, and align properly with clinical care, we recommend that Congress authorize CMS to convene an expert panel to determine how best to consider coverage decisions for these types of services to ensure patients maintain access to medically necessary testing and treatments.** We believe this will help prevent a repeat experience of continuously reopening an inadequately designed national coverage determination, which is unable to keep pace with developing science.

Coding

The National Correct Coding Initiative (NCCI) was developed by the Centers for Medicare and Medicaid Services (CMS) as a way to promote consistent national coding methodologies and to prevent improper coding and payments under Medicare Part B⁴. However, unlike other regulatory actions taken by CMS, there is no formal notice and comment period for NCCI revisions and manual edits, thereby denying appropriate stakeholder input

¹ <https://www.cms.gov/medicare-coverage-database/details/nca-tracking-sheet.aspx?NCAId=296>

² <https://www.amp.org/AMP/assets/File/AMP%20Comments-NCD%20on%20NGS-CAG-00450N-FINAL-1-17-2018.pdf?pass=23>

³ <https://www.amp.org/AMP/assets/File/advocacy/AMP%20Comments-ProposedNCD-Reconsideration-CAG-00450R-11-27-2019-FINAL.pdf?pass=3>

⁴ <https://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/index>

on this important process, which can significantly alter practice patterns and patient access to medically necessary services.

AMP and other stakeholders have expressed our concerns to CMS about the changes to the Pathology/Laboratory Services section of the NCCI Policy Manual, particularly the manual changes that became effective January 1, 2019 and were fundamentally disconnected from current laboratory testing practices^{5,6}. Like all NCCI edits, the updates are promulgated without the opportunity for public comment, and stakeholders are notified of these changes a few weeks before the effective date of the policies. Clinical laboratory and pathology testing services are very diverse—considering analyte, specimen types, and platforms. **As such, it is important that CMS consider stakeholder input when developing any revisions to the Coding Policy Manual and we recommend that Cures 2.0 include requiring NCCI edits and manual changes to be subject to notice and comment rulemaking.** This would give stakeholders time to review and to provide comments to CMS and to evaluate implementation of changes by Medicaid programs, which can take considerably longer to incorporate annual coding changes than Medicare.

PhD Billing for Molecular Pathology Procedures

Molecular pathology procedures involve multiple steps including preparation of the patient sample; performing the molecular diagnostic test; interpreting the results in the context of the patient; and ultimately preparing a comprehensive report for the treating physician and patient. Doctoral level (PhD or MD/DO) molecular laboratory professionals provide interpretation of the test in the context of a patient's medical history. As these testing procedures become increasingly more complex, and both the value and the need for these tests continue to increase, the imperative nature of the interpretive component of these services provided by molecular laboratory professionals is underscored. However, reimbursement for these interpretive services is currently lacking and several major hurdles exist.

Even though a substantial amount of the interpretation of molecular pathology testing is performed by professionals with PhDs, currently, only physicians (MD/DO degree holders) are able to be reimbursed by Medicare for clinical interpretation of molecular results. When professional interpretive work is not reimbursed, hospital administration may resist establishing in-house laboratory testing programs that enable the ordering/treating physicians and patients from interacting with those who interpret molecular tests.

AMP believes that doctoral scientists who have the required qualifications to interpret and report molecular pathology tests should be eligible to bill Medicare directly for these services. Since 2011, AMP has been a leading advocate for new legislation that would recognize appropriately-trained and board certified PhDs as Qualified Healthcare Professionals. We have actively worked on this issue with many professional organizations, including the American College of Medical Genetics and Genomics (ACMG), American Association for Clinical Chemistry (AACC), American Clinical Laboratory Association (ACLA), American Society of Clinical Pathology (ASCP), American Society for Histocompatibility and Immunogenetics (ASHI), and College of American Pathologists (CAP).

As molecular pathology procedures become increasingly more complex, and the value and the need for these tests continue to increase as the promise of precision medicine is realized, it is even more critical for these

⁵https://www.amp.org/AMP/assets/File/advocacy/AMP%20response%20to%20NCCI_February_28_2019.pdf?pass=57

⁶https://www.amp.org/AMP/assets/File/advocacy/Group_Stakeholder_Letter_NCCI_Edits_March_17_2019.pdf?pass=7

services to be interpreted by trained molecular laboratory professionals, who may include both physicians and qualified PhDs. **AMP recommends that Congress enact legislation to allow qualified non-physician doctoral scientists to bill Medicare directly for these molecular pathology interpretive services.** As CMS does not have the authority to add these providers by regulation in the absence of statute or executive order, we recommend that Congress should amend Section 1861(s) of the Social Security Act to designate non-physician doctoral scientists who have received the qualifications to interpret and report molecular pathology tests as Qualified Healthcare Professionals. This widely supported move will help ensure access to these important patient services and life-saving cures, and we hope you consider including this in Cures 2.0.

Incorporate H.R. 4393 Advancing Access to Precision Medicine Act in Cures 2.0

AMP believes that no patient should be denied access to a medically necessary test because of insurance coverage. Currently, CMS's reimbursement system has resulted in limited or non-coverage policies for many molecular procedures. Coverage policies developed by certain Medicare Administrative Contractors (MACs) often reverberate throughout the entire coverage landscape, both within the Medicare system and private health plans. AMP is supportive of methods that work to improve and expand coverage of molecular testing, particularly efforts that examine the value of molecular testing's utility beyond diagnosis of disease to other purposes including but not limited to predictive, prognosis, therapy selection, disease monitoring and recurrence. Thus, AMP recommends that Representative Swalwell's H.R. 4393, the *Advancing Access to Precision Medicine Act* be included in Cures 2.0.

H.R. 4393 requires the Department of Health and Human Services to enter into an arrangement with the National Academy of Medicine (NAM) for the academy to study usage of genetic and genomic testing, including how to reduce barriers to the utilization of such testing. The bill also allows individual states to apply for an exception to Medicaid's federal medical assistance percentage rate in order to provide whole genome sequencing clinical services to certain children, including those admitted to a pediatric intensive care unit for a chronic or undiagnosed disease and those suspected to have a pediatric-onset genetic disease.

AMP is very supportive of the work that has already been done by NAM's Roundtable on Genomics and Precision Health⁷, and as part of other related studies like the Evidence Framework for Genetic Testing⁸, which was commissioned by the Department of Defense. We are hopeful that NAM's work as outlined in H.R. 4393 would build upon these efforts and work to identify ways the government can improve access to these important tools that help guide and improve patient management and care, as well as how to better ensure reimbursement of medically relevant and necessary molecular testing.

While we applaud this effort, AMP does have some concerns about the reporting requirements for providers within this section and fear that the requirements may discourage laboratories from participating, diminishing effectiveness of this important effort for Medicaid patients. We have met with Rep. Swalwell's office in regards to this concern and his staff has been amenable to revising this language. We encourage you to include H.R. 4393 in a Cures 2.0 legislative initiative, with the recommendation that the reporting requirements be altered before the bill is finalized in order to ensure robust laboratory participation in this program. Additionally, AMP also recommends that this provision within Cures 2.0 allow for the coverage of genomic sequencing for children who have not yet been admitted to an intensive care unit. The average diagnostic odyssey for a child with a rare

⁷ <http://www.nationalacademies.org/hmd/Activities/Research/GenomicBasedResearch.aspx>

⁸ <https://www.nap.edu/catalog/24632/an-evidence-framework-for-genetic-testing>

disease is approximately five years, and all children with undiagnosed rare diseases, including those who are not in an intensive care setting, will benefit from greater access to this test.⁹

Implementation of the Protecting Access to Medicare Act

AMP believes that the Centers for Medicare and Medicaid Services' (CMS) implementation of Section 216 of the Protecting Access to Medicare Act (PAMA)¹⁰ is limiting patient access to innovative diagnostics by lowering reimbursement based on flawed data. PAMA required CMS to create a market-based pricing system for services on the Clinical Laboratory Fee Schedule (CLFS). In response, CMS implemented a process for gathering private payor data from laboratories and using it to establish the CLFS fee schedule in a three-year cycle. Since implementation of PAMA, one complete cycle of data collection and rate setting has been completed.

Based on the experience of the first cycle, AMP has significant concerns about both the process and outcomes, which resulted in inaccurate and inequitable pricing. Of the over two-hundred thirty (230) molecular pathology tests (including oncology, inherited diseases, and infectious diseases) on the CLFS, fifty-seven percent (57%) decreased in value from their 2017 National Limitation Amount (NLA). Ninety (90) molecular tests decreased in value by thirty percent (30%) or more. When AMP did an analysis of the publicly available data used in rate setting, we found data was included that appeared not to represent the actual cost of performing certain molecular pathology procedures. For example, a test that involves detecting an infectious agent by DNA or RNA identification was reported to have a cost of \$0.01 to perform by some laboratories. In reality, this test costs significantly more than \$0.01 to perform, suggesting that there is a catastrophic flaw in how laboratories reported data within the system, raising concerns about additional prices that may have been set by wildly inaccurate data.

AMP supports current efforts to address some of the many problems with PAMA, including the LAB Act (H.R. 3584), recently introduced by Rep. Scott Peters (D-CA), Rep. Gus Bilirakis (R-FL), Rep. Bill Pascrell (D-NJ), Rep. Kurt Schrader (D-OR), Rep. Richard Hudson (R-NC) and Rep. George Holding (R-NC). This bipartisan legislation addresses some of AMP and other stakeholders' concerns with PAMA. H.R. 3584 delays the next round of data reporting by one year and delays the timing for payment reductions under PAMA. These delays are important so that applicable laboratories have time to understand the reporting requirements, make preparations to accurately collect their data, and ensure those data are accurately reported to CMS. We support this effort and hope that this bill is passed before the end of the year¹¹.

However, we and other stakeholders realize that the LAB Act is not a long term solution to the myriad of issues PAMA has created for laboratories. As the effects of PAMA compound over time, laboratories will be forced to either restrict their test menu or close, resulting in reduced patient access to laboratory testing. Moreover, development of new, innovative testing will stall as there will be little incentive to add new tests for clinical use. Thus, the consequences of PAMA are working against efforts to increase access to life-saving cures in the United States, such as those desired by Reps. Upton and DeGette. We welcome the opportunity to work with Reps. DeGette and Upton to explore solutions that may help to ameliorate the effects of PAMA.

⁹ <https://www.globalrareiseasecommission.com/Report/assets/static/documents/GlobalCommission-print-021919-a68c8ce2a5.pdf>

¹⁰ Protecting Access to Medicare Act of 2014, H.R. 4302, 113th Congress. (2014)

¹¹ <https://www.amp.org/AMP/assets/File/advocacy/AMPLetter-LABAct-10-16-2019-FINAL.pdf?pass=20>

Thank you for the opportunity to provide these recommendations for inclusion in Cures 2.0. We acknowledge that there is a range of specificities regarding both the topics that we mentioned in these comments and the solutions that we propose. Our goal with these comments is to open the conversation regarding these topics so that stakeholders and the Reps. can come up with solutions. AMP aims to be a valuable resource as you consider these important topics. Please reach out to Tara Burke, Senior Director of Public Policy and Advocacy, at tburke@amp.org if you have any questions. We look forward to working with your offices as this important legislation is developed.

Sincerely,

Karen E. Weck, MD, FCAP
President, Association for Molecular Pathology