ASSOCIATION FOR MOLECULAR PATHOLOGY
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Elaine Jeter, MD
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Dear Dr. Jeter:

On behalf of the Association for Molecular Pathology (AMP), we are writing in response to the specifications entitled, *Analytic Performance Specifications for Comprehensive Genomic Profiling* (M00118, V1), recently posted on Palmetto's website. These specifications outline Palmetto's policies for reimbursement of NGS-based tests.

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 the government, academic medicine, private and hospital-based clinical laboratories, and the in vitro diagnostic industry.

AMP members currently design, perform, and interpret NGS-based testing in their labs and understand the promise this technology holds to revolutionize patients' access to targeted treatment and therapies. We recognize that Palmetto remains concerned about payment accuracy and medical necessity for molecular diagnostic testing. However, we do not believe that the article is either the appropriate or an effective way of addressing those concerns. Furthermore, it is not clear why Palmetto would release such a prescriptive policy for NGS-based testing. We do not understand what about this technology, in particular, warrants the restrictions outlined in this article. We are deeply concerned that this policy will limit patient access to these potentially lifesaving tests, and these concerns are outlined in detail below.

Publication of Policy Outside of LCD Process

AMP remains concerned that the process being employed by Palmetto to make decisions about molecular diagnostic tests for which coverage will be limited or excluded is insufficient to comply with the local coverage determination (LCD) process and routinely does not include relevant input from the medical community. Policy determinations, like those articulated in the specifications referenced above must be transparent and include an opportunity for stakeholders to comment publicly. This policy determination on NGS-based tests was released without such an opportunity, and it presented critical policy changes that will restrict coverage and unduly limit reimbursement. **We request that Palmetto re-release this policy in the form of a LCD with an open comment period for stakeholders.**

Furthermore, Section 216 of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub.L. 113-93) requires Medicare administrative contractors to use the LCD process for coverage policies applying to clinical diagnostic tests as of January 1 of this year. **As Palmetto continues to make coverage determinations as part of the MolDx program, we urge Palmetto to adhere to the requirement in PAMA for these tests and the policies related to these tests moving forward as it ensures that coverage decisions will not be finalized without public review and comment.**

Physician Reporting Requirement

Under current Centers for Medicare and Medicaid Services (CMS) reimbursement policies, PhDs and physicians can be reimbursed for molecular diagnostic tests; their placement on the Clinical Lab Fee Schedule (CLFS) ensures this. A requirement that only physicians can interpret and sign out NGS tests is inconsistent with CMS policy.

Section 1861(s)(3) of the Social Security Act (SSA) defines medical and other health services to include the following:

> *Diagnostic X-ray tests (including tests under the supervision of a physician, furnished in a place of residence used as the patient's home, if the performance of such tests meets such conditions relating to health and safety as the Secretary may find necessary and including diagnostic mammography if conducted by a facility that has a certificate (or provisional certificate) issued under section 354 of the Public Health Service Act[217]),* ***diagnostic laboratory tests****, and other diagnostic tests.*

Under the SSA, diagnostic laboratory tests are defined separately from physician services. Medicare does not reimburse the physician or PhD for these diagnostic laboratory tests, rather the laboratory is reimbursed under the CLFS. Furthermore, Chapter 16, Section 40 of the Medicare Claims Processing Manual outlines the requirements for laboratories to bill for laboratory tests under the CLFS. Allowing physicians only to bill for these diagnostic tests runs contrary to the language of the SSA and the Medicare Claims Processing Manual, which clearly show that laboratories themselves bill for these tests.

Furthermore, molecular pathology and gene sequencing procedures were placed on the CLFS rather than the Physician Fee Schedule (PFS) PhDs interpret and sign out these tests. The 2013 CMS Physician Fee Schedule Final Rule says:

> *Molecular pathology CPT codes describe clinical diagnostic laboratory tests that should be paid under the CLFS because these services do not ordinarily require interpretation by a physician to produce a meaningful result. While we recognize that these tests may be furnished by a physician, after reviewing the public comments and listening to numerous presentations by stakeholders throughout the comment period, we are not convinced that all these tests ordinarily require interpretation by a physician.*

Palmetto's policy clearly violates this policy. As you know, allowing both PhDs and MDs to continue to provide these professional services ensures that patients receive these tests in the most efficacious manner possible.

Directors of clinical testing laboratories that are certified by CLIA to provide high complexity testing are either physicians or qualified doctoral scientists. Such qualified doctoral scientists possess a doctoral-level degree such as a PhD in biochemistry, genetics, molecular biology, or other life science fields. They hold professional board certification and licensure to practice where required. Doctoral scientists are held to rigorous professional standards by their medical institutional employers and by the medical community and are subject to many of the same laws and regulations regarding the interpretation and reporting of these molecular tests as are physicians.

CMS' CLIA regulations specifically authorize PhDs to serve as laboratory directors:

§ 493.1443 Standard: Laboratory director qualifications.

(b) The laboratory director must—
(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution and—
(i) Be certified and continue to be certified by a board approved by HHS; or
(ii) Before February 24, 2003, must have served or be serving as a director of a laboratory performing high complexity testing and must have at least—
(A) Two years of laboratory training or experience, or both; and
(B) Two years of laboratory experience directing or supervising high complexity testing.

As authorized by CLIA, many NGS tests are interpreted and signed out by appropriately qualified and board-certified PhD scientists. By prohibiting PhD scientists from providing these tests, Palmetto's policy contradicts CLIA, which will severely limit patient access in the process. **Palmetto must rescind this policy to realign with CLIA and allow PhD scientists to continue to provide NGS testing in its jurisdiction.**

Requirement that Tests Be Reviewed by CAP or NYDOH

This policy arbitrarily ties a facility's accreditation origin to coverage and reimbursement for an individual test. We believe this is unreasonable. Many hospital-based labs choose to be accredited by the Joint Commission for a number of reasons, including the preference to deal with only one accrediting body, affordability, and other non-lab quality related reasons. Participation in the College of American Pathologist's (CAP's) proficiency testing (PT) program is open to laboratories accredited by organizations other than CAP. In addition, the CAP checklists used in its own accreditation program are available for purchase by laboratories not in its accreditation program. **We recommend that Palmetto eliminate this requirement.**

Introduction of Strict Testing Limitations which Exceed CAP's Requirements

The NGS testing requirements outlined in this article are substantially more limiting than those implemented by the College of American Pathologists (CAP). Therefore, Palmetto's policy mandates technical molecular oncology NGS requirements before they have been established by experts in the field. For example, mandating the number of samples tested per variant type, benchmarks for variant allele frequencies, specific sample mixing experiment benchmarks, or the National Institutes of Standards and Technology (NIST) standardized reference material analysis are not included in the CAP NGS checklists. CAP does not use such prescriptive requirements because: "given the reality of this rapidly changing technology, and because NGS-based tests can be varied depending on type of tests and scale of analysis, the NGS Work Group developed general requirements for a variety of NGS clinical testing scenarios to allow laboratories flexibility and latitude in individual approaches to meeting the requirements, while at the same time providing much needed regulatory standards." (*Archives in Pathol Lab Med* Vol 139, Apr 2015 http://www.archivesofpathology.org/doi/full/10.5858/arpa.2014-0250-CP)

Additionally, CAP's "work group elected to not prematurely introduce requirements on NGS topics that would benefit from further technology evolution and/or deliberation and consensus building at the professional society level for specific disciplines." (*Archives* paper) By employing the scorecard approach outlined in this article, Palmetto has established discrete validation requirements ahead of the specialty societies and without the consensus of subject matter experts in NGS testing. We believe that this is an unreasonable, preemptive approach that will have the negative consequences outlined above.

The validation requirements being imposed by Palmetto would potentially be prohibitively expensive to complete, in terms of both labor and materials. In conjunction with the fact that labs are faced with diminishing reimbursements and a number of the new gene sequencing procedure CPT codes are not being priced at all, cost is a serious barrier. With fewer labs offering fewer types of panels, there will of course be decreased access for those patients whose medical centers are only able to offer single gene tests. As these services are consolidated in fewer laboratories, there is the potential for longer turnaround times and increased costs to the referring hospital. **For these reasons, we urge Palmetto to eliminate these NGS testing restrictions.**

Thank you for your careful review of these concerns. We would be happy to discuss these issues with you in more detail and look forward to having the opportunity to formally comment on this policy in a forthcoming draft LCD. Please direct your correspondence to Mary Steele Williams, AMP Executive Director, at mwilliams@amp.org.

Sincerely,

Janina A. Longtine
AMP President