**ASSOCIATION FOR MOLECULAR PATHOLOGY**
*Education. Innovation & Improved Patient Care. Advocacy.*
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April 11, 2018

Ms. Virginia Muir
LCD Comments
P.O. Box 7108
Indianapolis, IN 46207-7108
PartBLCDComments@anthem.com

Re: Draft Local Coverage Determination: Administrative Multianalyte Assays with Algorithmic Analyses (MAAA) and Proprietary Laboratory Analyses (PLA) Services (DL37600)

Dear Ms. Muir:

The Association for Molecular Pathology (AMP) is pleased to offer these comments in response to your draft local coverage determination entitled Administrative Multianalyte Assays with Algorithmic Analyses (MAAA) and Proprietary Laboratory Analyses (PLA) Services (DL37600). AMP is an international medical professional association representing approximately 2,400 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 and commercial clinical laboratories, community hospitals, and the in vitro diagnostics industry.

AMP recognizes the challenge facing National Government Services (NGS) to evaluate and determine coverage for all of the administrative MAAA and PLA services. AMP also recognizes that PLA codes are different in their prerequisite criteria than AMA Category 1 CPT codes and require a different process to incorporate into existing coding, coverage and pricing processes. At the same time, AMP anticipates that PLA code set adoption will increase over time and believe it is important to provide an appropriate path to coverage that does not limit patient access to emerging highly valuable care.

AMP supports NGS' practice of applying a consistent evidentiary standard for all molecular tests that are evaluated for coverage. AMP shares NGS' concern that patients should have access to the administrative MAAA and PLA services that meet that coverage standard, and AMP would welcome the opportunity to work with NGS to ensure patient access to appropriate testing in the NGS jurisdiction.

However, AMP at this time has concerns about the approach to coverage of emerging services outlined in this proposed policy and believe, as currently drafted, that it may lead to a delay in patient access to medically necessary and reasonable procedures. The policy states "Administrative MAAA and PLA services are not considered medically reasonable and necessary by default at the time of issue." The policy then proposes to evaluate requests for coverage in accordance with the LCD reconsideration process. While in some cases coverage may not be warranted, it is important to note that some PLA codes were previously reported under a Category 1 CPT code before the clinical laboratory chose to pursue and subsequently received a PLA code. Test providers are no longer allowed to report the Category 1 code once they receive a PLA code. For example, the procedure described under PLA code 00016U encompasses services described under the CPT codes 81206 and 81207. The American Medical Association provides the following guidance:

> When a PLA code is available to report a given proprietary laboratory service, that code takes precedence. The service should not be reported with any other CPT code(s) and other CPT code(s) must not be used to report services that may be reported with that specific PLA code[i].

Thus, AMP is concerned that the proposed approach outlined in the draft policy will at least temporarily eliminate coverage for PLA services previously covered using Category 1 CPT codes and impose an unnecessary burden and obstacle to maintain continuous coverage. For labs requesting and receiving a PLA code, there is no workaround to a gap in coverage for their services, and there is no process for recapturing the lost revenue or guarantee of a timeline or outcome to a request for reconsideration.

**AMP recommends that NGS develop an expedited process, different than reconsideration, for laboratories either to propose equivalency between their PLA code and existing CPT codes, or to submit evidence for services provided under administrative or PLA codes without requiring them to go through the reconsideration process.** Our leadership and members in the NGS jurisdiction would welcome the opportunity to work with you to implement this.

We respectfully ask that you consider these comments, which were prepared by members of AMP who provide services to Medicare beneficiaries covered by NGS. We are happy to be of assistance in providing additional clinical information, references, contacts, or whatever is needed to assist you with this draft LCD. Please direct your 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

[i] https://www.ama-assn.org/practice-management/faq-cpt-pla