AMA
AMERICAN MEDICAL ASSOCIATION

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Ms. Virginia Muir
National Government Services
LCD Comments
P.O. Box 7108
Indianapolis, IN 46207-7108

RE: Proposed LCD DL37600: Administrative Multianalyte Assays with Algorithmic Analyses (MAAA) and Proprietary Laboratory Analyses (PLA) Services

Dear Ms. Muir:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments on the proposed Local Coverage Determination (LCD) (DL37600) that was recently issued by National Government Services (NGS). I would also like to provide clarifications on the Current Procedural Terminology® (CPT®) criteria for Category I, Administrative Multianalyte Assays with Algorithmic Analyses (MAAA), and Proprietary Laboratory Analyses (PLA) Services codes. The draft LCD proposes that clinical tests with CPT Administrative MAAA or PLA codes will not be covered unless a reconsideration request demonstrates that the testing services are medically necessary and reasonable.

We are concerned that a blanket non-coverage determination for a potentially broad and varied set of clinical tests without regard to existing clinical evidence will delay patient care and place burdens on patients and providers seeking medically necessary and reasonable medical services. We appreciate that NGS has proposed that a request for reconsideration may be submitted to establish that a clinical test is medically necessary and reasonable and that this may reflect NGS's preference for an existing process to make this assessment. However, we anticipate that this will unduly delay access to patients where clinical evidence exists to support coverage. An orderly process to assess medical necessity and reasonableness should be established without defaulting to the processes for reconsideration which can be time consuming and bureaucratic. Specifically, providers and developers of clinical tests should have a well-defined and transparent process by which they are able to submit relevant evidence that would establish medical necessity and reasonableness without delaying patient care. Clinical testing is often central to diagnosis, prognosis, or adjustment of therapeutic treatments, and delays may deter use of medically necessary and reasonable clinical testing options or may have a deleterious impact on patient care and outcomes during the pendency of a reconsideration request. We are also very concerned that utilizing the reconsideration process in this manner will slow down the processing of other reconsideration requests for other services as the number of tests with PLA codes may increase significantly given the advances in next generation sequencing.

Even though in some cases coverage may not be appropriate, the section of the draft LCD DL37600 captioned "Analysis of Evidence" does not contain evaluation of clinically relevant evidence in support of

existing or future clinical tests with administrative MAAA or PLA codes as is required for issuance of an LCD. Instead, the rationale for the presumption of non-coverage provides that administrative MAAA and PLA codes are not required to meet an evidentiary standard and therefore are presumed to be not reasonable and necessary. However, there are clinical tests with PLA codes for which clinical evidence has been developed that would support a finding of reasonable and necessary. For example, a subset of these clinical tests could have reported applicable Category I codes, but have been granted PLA codes at the request of the clinical test providers and now cannot report the Category I code. Under this LCD, those test codes would be presumed non-covered by default unless a stakeholder files a request for reconsideration to demonstrate otherwise. The foregoing would be the case even where clinical evidence exists and had they not requested and received a PLA code, the applicable Category I code would apply.

Also, it is important to clarify that the Category I code criteria does not require evidence of clinical utility though clinical efficacy is considered as well as whether the service is consistent with current medical practice. (Incidentally, different health insurers do not use the same criteria or evidentiary requirements to define utility.) The following are the general and specific applicable criteria for Category I codes:

General Criteria for Category I and Category III Codes

- The proposed descriptor is unique, well-defined and describes a procedure or service which is clearly identified and distinguished from existing procedures and services already in CPT.
- The descriptor structure, guidelines and instructions are consistent with current editorial panel standards for maintenance of the code set.
- The proposed descriptor for the procedure or service is neither a fragmentation of an existing procedure or service nor currently reportable as a complete service by one or more existing codes (with the exclusion of unlisted codes). However, procedures and services frequently performed together may require new or revised codes.
- The structure and content of the proposed code descriptor accurately reflects the procedure or service as typically performed. If always or frequently performed with one or more other procedures or services, the descriptor structure and content will reflect the typical combination or complete procedure or service.
- The descriptor for the procedure or service is not proposed as a means to report extraordinary circumstances related to the performance of a procedure or service already described in the CPT code set.
- The procedure or service satisfies the category-specific criteria set forth below.

Specific Criteria for Category I Codes

A proposal for a new or revised Category I code must satisfy all of the following criteria:

- All devices and drugs necessary for performance of the procedure of service have received FDA clearance or approval when such is required for performance of the procedure or service.
- The procedure or service is performed by many physicians or other qualified health care professionals across the United States.
- The procedure or service is performed with frequency consistent with the intended clinical use (i.e., a service for a common condition should have high volume).
- The procedure or service is consistent with current medical practice.

- The clinical efficacy of the procedure or service is documented in literature that meets the requirements set forth in the CPT code-change application.

As noted above, if a PLA code exists for a test and it also can be described with an existing CPT Category I code, the Category I code cannot be used. When a PLA code is available to report a given proprietary laboratory service, that PLA code takes precedence. The service must 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.

The AMA appreciates that the PLA section of the CPT code set is relatively new. This section of the code set was developed to offer a solution that addressed the coding requirements of the Protecting Access to Medicare Act clinical laboratory fee schedule provisions. It is expected that providers must meet the coverage requirements of a health insurer based on available evidence. The AMA supports efforts to ensure services meet the established coverage requirements. However, the draft LCD imposes an onerous process for establishing coverage without considering the available evidence or medical necessity and reasonableness as part of this LCD and in the future outside of the reconsideration process. The AMA strongly urges NGS to develop a process that allows for the submission of evidence for clinical tests with PLA or Administrative MAAA codes that does not involve the reconsideration process, but allows for a rapid, transparent, and streamlined submission of available evidence in support of coverage.

Thank you for the opportunity to provide these comments. Please feel free to contact Shannon Curtis, Assistant Director of Federal Affairs, shannon.curtis@ama-assn.org or 202-789-8510, if you have any questions concerning these comments.

Sincerely,

James L. Madara, MD