American Clinical Laboratory Association

## Comment to Centers for Medicare & Medicaid Services on New Genetic Codes

## Monday, July 18, 2011

The American Clinical Laboratory Association (ACLA) is pleased to provide comments to the Centers for Medicare and Medicaid Services (CMS) on new genetic CPT codes being developed by the American Medical Association. ACLA is an association representing clinical and anatomic pathology laboratories throughout the country, including local, regional, and national laboratories. As providers of diagnostic testing services to Medicare beneficiaries, including genetic and molecular services, ACLA member companies will be directly impacted by these sweeping code changes.

ACLA appreciates that CMS is asking for stakeholder input on how these new genetic test codes should be addressed before CMS requests payment recommendations for these services. Specifically, CMS is seeking stakeholder input about the types of tests that should be assigned to the clinical laboratory fee schedule (CLFS) versus the physician fee schedule (PFS); how current CPT codes can best reflect the methods involved in genetic tests; and how new genetic tests may be similar to or different from currently reimbursed laboratory tests.

Threshold Issue

ACLA will address those questions. But first, it is of utmost importance that CMS ensure continued access to genetic and molecular diagnostics in a manner that provides for their reimbursement at a level commensurate with the value they add to patient care, without creating unintended consequences. These tests represent advancements and enhancements to quicker and more precise diagnostic and therapeutic procedures, and are instrumental contributions to realize the promise of better more effective care for Medicare beneficiaries. The stated purpose of these coding changes was merely to provide more coding transparency for these services, and ACLA supports that goal. To be consistent with this stated purpose, implementation of the changes should be administrative in nature, not a means by which CMS reallocates market share or otherwise seeks to alter the economics of molecular genetic testing services. Failure to adhere to these standards could result in unintended consequences such as significant disruption of clinical laboratory operations or disservice to non-physician doctoral providers – both of which would have negative implications for Medicare beneficiaries. ACLA's comments identify those unintended consequences and offer solutions to those problems.

Fee Schedule Placement

1100 New York Ave., NW • Suite 725 • Washington, DC 20005 • (202) 637-9466 • (202) 637-2050

In responding to the question of what are the types of tests that should be assigned to the clinical laboratory fee schedule versus the physician fee schedule, it will be valuable to briefly review the distinction between the two Medicare fee schedules and to consider how AMA's CPT system influences the question.

Commonly, anatomic pathology services are developed with a code division into "professional interpretation" payments and "technical component" payments. This signals PFS placement and allows for the physician to bill for his/her professional service or to bill globally for his/her interpretation and the technical component work that is performed by the clinical laboratory professional staff. Alternatively, most clinical laboratory tests that report a result — such as glucose, lipids, electrolytes etc. — are assigned to the CLFS and billed by the clinical laboratory as a Medicare provider. Although the laboratory services text of the AMA's CPT manual does not usually explicitly distinguish between physician pathology services and clinical laboratory services, one can discern the AMA opinion of fee schedule classification from the professional component (PC)/ technical component (TC) context of the CPT code.

On what fee schedule should molecular and genetic services be placed? This is not an easy or straightforward question to answer. Molecular genetic services are high complexity tests that, with the exception of microarrays, currently are placed on the CLFS. They are variously performed and interpreted by a qualified Ph.D. healthcare professional[1], by a M.D. pathologist, by a mix of both professionals or, in some cases, can utilize an automated computer system to aid in generating an analysis. In all cases, in order to be effective for patient care an interpretative function is required. Ordering providers will not understand the clinical significance of a list of genetic mutations or aberrations without interpretation performed by qualified laboratory professionals.

ACLA surveyed its membership to determine how this interpretive function is being performed and who is performing the interpretation in ACLA's member laboratories. The survey included all 180 tier 1 and 2 codes that have been finalized by AMA. ACLA members provided results for 93% of the 180 codes surveyed; therefore, this survey represents a large volume of these services. The results indicate;

- 99% of the time the TC of the test was performed by a laboratory technician.
- 100% of the time there was a separate interpretation performed.
- 90% of the time that interpretation is performed by a PhD; 10% by a pathologist and 1% computer assisted

The results indicate that PhD healthcare professionals are predominately providing the interpretative result**.** Assuming that the PFS cannot accommodate a payment mechanism to reimburse providers for services interpreted by qualified healthcare professionals other than physicians, these facts would suggest that these services belong on the CLFS.

---

[1] A "qualified healthcare professional" (i.e., "qualified non physician healthcare professional") is an individual who by education, training, licensure/regulation, facility credentialing (when applicable) and payer policy is able to perform a professional service within their scope of practice and independently report a professional service. These professionals are distinct from "clinical staff". A clinical staff member is a person who works under the supervision of a physician or other qualified healthcare professional and who is allowed by law, regulation, facility, payer policy to perform or assist in the performance of specified professional services, but who does not individually report any professional services.

The new AMA genetic codes generally recognize the need for a physician or other qualified healthcare professional interpretation. On the basis that an interpretation is required, it might be assumed that the AMA codes would be characterized (with a few exceptions) as PC/TC services, and therefore would most likely be considered for the physician fee schedule. However, that placement assumption can be challenged on multiple grounds. First, it does not consider the frequency with which the interpretation ordinarily requires performance by a physician and the frequency with which it is furnished by a non-physician health care professional. Second, while the CLFS does not currently include an interpretive code that requires medical judgment, it does currently include a technical interpretive molecular CPT code, 83912. Further, the new molecular CPT codes are designed to represent the same interpretive service for the technical procedure regardless of whether or not it requires medical judgment, because it covers interpretations performed by either a physician or a non-physician health care professional.

Setting aside whether the PFS is a correct placement, the problem that PFS assignment presents for clinical laboratory operations is that current CMS policy does not recognize non-physician healthcare professionals (Ph.D. Molecular Geneticist Scientists) as qualified healthcare professionals who can bill CMS directly under the PFS for interpretative services (PC). Therefore, laboratories that currently rely on qualified Ph.D. healthcare professionals for interpretation of molecular tests currently reimbursed under the CLFS will have difficulty receiving reimbursement for these services if they are assigned to the PFS. Placement on the PFS also presents problems for the clinical laboratory to bill and be paid for TC services performed by non-physician doctoral providers, especially if the new codes are designated by CMS as “global” rather than stand alone technical and professional components. Unless an exception is made (as CMS has done with microarray testing), services placed on the physician fee schedule arguably might require performance of the professional component by a physician in order for EITHER the professional or technical components to be reimbursed. Consequently, if laboratories cannot bill the professional component because the interpretation has been provided by a Ph.D. healthcare professional, the technical component may also not be paid. Unless addressed by CMS, this could lead to the untenable result that those laboratories currently providing the bulk of molecular testing may be left without a mechanism for receiving any payment for their services. Because laboratories cannot be expected to provide molecular testing services for free (and perhaps may be legally prohibited from doing so), the cost would either have to be borne by Medicare beneficiaries or the service would not be provided. Such a result would have obvious negative implications for patient access and patient care.

Current Coding

In thinking about how current CPT codes can best reflect the methods involved in genetic tests, it will be of value to review how interpretative results for genetic test services are currently coded. The physician’s clinical interpretation of a molecular test result is generally billable by a pathologist (or other physician) using CPT code 83912 with modifier -26 (interpretation and report) or, when a consult of an abnormal test result is requested by the patient’s attending physician, using codes 80500 (clinical pathology consultation, limited) or 80502 (comprehensive consultation of complex diagnostic problem). Interpretation is billable by a non-physician (through their clinical laboratory provider) using code 83912. Physicians as well as non-physician Ph.D. healthcare

professionals who interpret and report molecular results can bill the technical component of 83912. ACLA understands that CPT code 83912 will be deleted when the AMA molecular pathology coding initiative is complete.

Genetic Tests Have Unique Characteristics to Currently Reimbursed Laboratory Tests

From the above discussion, molecular tests have characteristics and operational elements that bridge both fee schedules. They require a complex interpretative function predominately performed by non-physicians, in some cases analysis is aided by computer systems and in some cases may benefit from clinical interpretation by pathologists. ACLA has proposed solutions that would allow payment and would preserve flexibility in payment options, while preserving the general coding scheme otherwise being advanced by AMA.

Proposed Solutions

The following main points are ACLA's proposed solutions;

- Each new genetic code should be assessed individually to determine how the interpretative function is most commonly performed – by a pathologist, a non-physician or by advanced computer systems. This may require a more systematic process by CMS to gain all stakeholders input.

- If the interpretation is most commonly performed by non-physician doctoral healthcare professionals, the code should be placed on the CLFS and CMS should either work with stakeholders to develop a new CLFS code that will allow non-physician healthcare professionals to bill for the interpretive function or continue CPT 83912, but fully recognize the value of the service being provided.

- If the interpretation is most commonly performed by pathologists, the code should be placed on the PFS as a PC/TC service and CMS should develop a policy that would allow suppliers of such services to bill and receive payment for the technical component under the PFS, notwithstanding that the services were performed and interpreted by qualified Ph.D. healthcare professional rather than physicians. CMS has already established precedent for this solution with respect to array-based evaluations of multiple molecular probes.

- If the interpretation is most commonly performed by an advanced computer system, the code should be placed on the CLFS recognizing that advanced analysis should be additionally valued as part of the fee schedule payment.

- While it is the position of some ACLA members that the foregoing analysis supports assignment of most of the new codes to the CLFS, if CMS adopts all the new AMA genetic codes under the PFS, it should do so as analyte-specific, standalone technical component codes with separate PC codes to reflect the level of complexity of physician or other qualified profession interpretive services. CMS should administratively recognize and allow qualified non-physician healthcare professionals to bill for interpretive services. CMS is not prohibited from having standalone technical component codes for which there is no physician work component on the physician fee schedule. Such codes can be

billed by suppliers of such services without reference to a professional component.

AMA has initiated a massive coding and valuation reconfiguration that will impact over 1000 clinical laboratory molecular pathology services. ACLA appreciates CMS's request for stakeholder input and asks that no action in this area be finalized until 2013 to allow for the needed clinical laboratory operations transition and to minimize impact on Medicare beneficiaries. ACLA will be pleased to discuss or submit to CMS more detail on our proposed solutions and appreciates the opportunity to provide input on this very important issue.

.

1100 New York Ave., NW • Suite 725 • Washington, DC 20005 • (202) 637-9466 • (202) 637-2050