



September 18, 2009

Glenn McGuirk  
Centers for Medicare and Medicaid Services  
Baltimore, MD.

Dear Mr. McGuirk:

The American Clinical Laboratory Association (ACLA) is pleased to have the opportunity to provide additional comment and offer recommendations to the Centers for Medicare and Medicaid Services (CMS) in connection with its assignment of payment rates for 2010 clinical laboratory CPT codes. ACLA is an association representing independent clinical laboratories, including local, regional and national laboratories. All ACLA members furnish services to Medicare beneficiaries; therefore, ACLA members will be directly affected by the payment levels established for these new codes.

ACLA would like to ask for a reconsideration of the 2010 NLA CMS proposes for Procalcitonin (PCT). Our organization continues to support the crosswalk to 83880 for 8414X Procalcitonin, with an NLA of \$49.56, as proposed during the July 14<sup>th</sup> public comment meeting.

Procalcitonin (PCT) can be produced by numerous cell types and organs after proinflammatory stimulation, particularly when caused by bacterial challenge. Procalcitonin is not found in the serum of healthy individuals; however, in response to bacterial infections, a rapid rise in serum PCT levels occurs. Procalcitonin has been identified as a biomarker that may assist in distinguishing bacterial infection from other causes of fever or sepsis (e.g. viral infections) that do not lead to an increase in serum PCT levels. The level of PCT in the serum is reportedly a reflection of the severity of bacterial infection, ranging from slightly elevated in infections with minor systemic inflammatory response to very high values in cases of severe sepsis and septic shock. Once an infection is under control, PCT levels decrease.

There are several FDA approved procedures used to quantitate PCT in serum or plasma. These utilize different technologies and instruments to obtain quantitative results. All assays have a similar indication for use, which is to aid in the assessment of risk progression to severe sepsis and septic shock in critically ill patients in the emergency department or an intensive care unit. The assays are intended to be used in conjunction with other laboratory findings and clinical assessments to determine whether an infection is bacterial or viral, thus, potentially avoiding unnecessary use of antibiotics.

The resources required to perform a PCT procedure are considerably more than the CMS proposed NLA of \$28.30. The fact that this test is usually run as a stat procedure in itself increases the cost due to the interruption of the routine workflow of collecting the sample, running it immediately vs. batch-wise and reporting the results quickly. Plus, the approximate cost to perform a single test is \$50.00-65.00, depending on the device and instrumentation.

ACLA would also like to comment on the two new G-codes for drug screens that were added late to the agenda for the public comment meeting. ACLA is in agreement with the NLA recommendations proposed by CMS for the two new HCPCS G-codes for drug screens, GXXX1 and GXXX2. However, we do have some concerns regarding the implementation date and utility of those codes and would like to comment.

It is our understanding that the implementation date for the two new G-codes is Jan. 1, 2010. ACLA is of the opinion that this date is premature and should be extended. The two G-codes were added to the CLFS meeting agenda late, one week prior to the meeting. This late notice did not allow providers adequate time to gain a thorough understanding of the intent of the codes. While we understand CMS's need to make changes, we would like to recommend that the changes occur once the industry has been well informed and there is a clear understanding of how to utilize the codes.

In addition to requesting that there be a delay in the implementation date, ACLA would like to verify our understanding of the intent of the two new G-codes for drug testing. Drug testing is complex due to the various methodologies and platforms available today. Therefore, we request that you provide confirmation that we have a clear understanding of the coding CMS expects to receive as specially noted below:

#### **GXXX1 Drug screen, qualitative; multiple drug classes, any method, each procedure**

It is our understanding that this code represents any number of drug classes performed by a single procedure. One example is an eight-drug immunoassay dipstick method

where all eight of the dipsticks are introduced into the sample at the same time and eight results are reported. The GXXX1 code would be assigned with one as the unit of service.

Another example could be a drug screen by fluorescence immunoassay designed to detect 10 different drug classes. In this example the urine is added to a reaction vessel that contains the reagents for all 10 drugs. This vessel is inserted into an instrument, which reads the positive or negative reactions for each drug. The GXXX1 with one unit of service would be assigned because this is a single procedure for multiple drug classes.

A third example would occur in the event that two different chromatography procedures are required to perform a drug screen for five drugs. These are not your usual drugs of abuse but those that are more esoteric in nature and require different methodologies for detection. A gas chromatography and a thin layer chromatography are performed. In this example one would report GXXX1 x2 for the two different procedures.

**GXXX2 Drug screen, qualitative; single drug class method (e.g., immunoassay and enzyme assay), each drug class**

It is our understanding that this code represents a single drug class performed by any method. One application of this code is a five-drug screen performed on a random access analyzer utilizing five different EIA procedures. The codes for this testing scenario would be GXXX2 (x5) units of service, one unit for each drug.

In summary, ACLA requests that CMS reconsider their original proposed crosswalk to 84146 Prolactin and crosswalk PCT to the more appropriate 83880 Natriuretic Peptide with an NLA of \$49.56. We further request that CMS delay the implementation date for the two new G-codes so that important questions regarding the utilization of these codes can be fully considered and understood.

Thank you for the opportunity for this additional comment period and please contact us with any questions.

Sincerely,

David Mongillo